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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 001-40545

CVRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**41-1983744**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

9201 West Broadway Avenue
Suite 650
Minneapolis, MN 55445
(Address of Principal Executive Offices)

(763) 416-2840
(Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	**CVRX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐		
Non-accelerated filer	☒	Smaller reporting company	☒	Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 08, 2021, there were 20,351,779 shares of the registrant's common stock, par value $0.01 per share outstanding.

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CVRx, Inc.
Quarterly Report on Form 10-Q
For the quarterly period ended September 30, 2021

Cautionary Note on Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements, including statements regarding our future results of operations and financial position, business strategy, the impact of the ongoing and global COVID-19 pandemic on our business, financial results and financial position, clinical trial results, prospective products, product approvals, research and development costs, timing and likelihood of success, and the plans and objectives of management for future operations.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, the important factors discussed in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q, which are summarized below. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include, but are not limited to, the following:

- we have a history of significant losses, which we expect to continue, and we may not be able to achieve or sustain profitability;
- our principal stockholders, management and directors (four of whom are affiliated with our principal stockholders) own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval;
- we have a limited history operating as a commercial company and are highly dependent on a single product, BAROSTIM NEO, and the failure to obtain market acceptance in the U.S. for BAROSTIM NEO would negatively impact our business, liquidity and results of operations;

- we have limited commercial sales experience marketing and selling our BAROSTIM NEO, and if we are unable to establish and maintain sales and marketing capabilities, we will be unable to successfully commercialize our BAROSTIM NEO or generate sustained and increasing product revenue;
- we must demonstrate to physicians and patients the merits of our BAROSTIM NEO;
- if third-party payors do not provide adequate coverage and reimbursement for the use of BAROSTIM NEO, our revenue will be negatively impacted;
- our industry is competitive; if our competitors, many of which are large, well-established companies with substantially greater resources than us and have a long history of competing in the heart failure market, are better able to develop and market products that are safer, more effective, less costly, easier to use or otherwise more attractive than BAROSTIM NEO, our business will be adversely impacted;
- if we fail to receive access to hospitals, our sales may decrease;
- we are dependent upon third-party manufacturers and suppliers, and in some cases a limited number of suppliers, making us vulnerable to supply shortages, loss or degradation in performance of the suppliers and price fluctuations, which could harm our business;
- manufacturing risks may adversely affect our ability to manufacture our product and could reduce our gross margin and profitability;
- a pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business;
- we may face product liability claims that could be costly, divert management's attention and harm our reputation;
- we may in the future become involved in lawsuits to protect or enforce our intellectual property, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively commercialize our existing or future products;
- if we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel; and
- we will continue to obtain long-term clinical data regarding the safety and efficacy of our products, which could impact future adoption and regulatory approvals.

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

CVRx, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 170,913	$ 59,112
Accounts receivable, net	3,421	1,281
Inventory	3,440	3,343
Prepaid expenses and other current assets	2,923	605
Total current assets	180,697	64,341
Property and equipment, net	943	410
Other non-current assets	67	26
Total assets	$ 181,707	$ 64,777
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 541	$ 483
Accrued expenses	4,977	3,583
Warrant liability	—	3,911
Current portion of long-term debt	3,333	—
Total current liabilities	8,851	7,977
Long-term debt	16,151	19,278
Other long-term liabilities	941	777
Total liabilities	25,943	28,032
Commitments and contingencies		
Convertible preferred stock, $0.01 par value, 10,000,000 and 237,370,645 authorized as of September 30, 2021 and December 31, 2020, respectively; 0 and 223,541,754 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	329,983
Stockholders' equity (deficit):		
Common stock, $0.01 par value, 200,000,000 and 625,217,795 authorized as of September 30, 2021 and December 31, 2020, respectively; 20,351,779 and 360,412 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	204	4
Additional paid-in capital	539,941	58,624
Accumulated deficit	(384,184)	(351,676)
Accumulated other comprehensive loss	(197)	(190)
Total stockholders' equity (deficit)	155,764	(293,238)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 181,707	$ 64,777

The accompanying notes are an integral part of these condensed consolidated financial statements.

CVRx, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue	$ 3,395	$ 997	$ 9,378	$ 3,965
Cost of goods sold	876	212	2,656	989
Gross profit	2,519	785	6,722	2,976
Operating expenses:				
Research and development	1,699	1,500	5,704	5,900
Selling, general and administrative	8,111	2,327	18,198	6,455
Total operating expenses	9,810	3,827	23,902	12,355
Loss from operations	(7,291)	(3,042)	(17,180)	(9,379)
Interest expense	(614)	(621)	(1,823)	(1,856)
Other income (expense), net	1,795	455	(13,439)	592
Loss before income taxes	(6,110)	(3,208)	(32,442)	(10,643)
Provision for income taxes	(23)	(19)	(66)	(64)
Net loss	(6,133)	(3,227)	(32,508)	(10,707)
Cumulative translation adjustment	(3)	14	(8)	(7)
Comprehensive loss	$ (6,136)	$ (3,213)	$ (32,516)	$ (10,714)
Net loss per share, basic and diluted	$ (0.30)	$ (9.56)	$ (4.66)	$ (27.58)
Weighted-average common shares used to compute net loss per share, basic and diluted	20,126,672	360,356	6,975,386	396,071

The accompanying notes are an integral part of these condensed consolidated financial statements.

CVRx, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)
(Unaudited)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount				
Balances as of June 30, 2021	223,541,754	$ 329,983	366,342	$ 4	$ 59,311	$ (378,051)	$ (195)	$ (318,931)
Exercise of stock options	—	—	5,853	—	8	—	—	8
Employee stock compensation	—	—	—	—	474	—	—	474
Issuance of common stock, net of offering costs	—	—	8,050,000	81	133,080	—	—	133,161
Reverse stock split	—	—	—	—	(1)	—	—	(1)
Conversion of Series G preferred stock	(223,541,754)	(329,983)	11,929,584	119	347,069	—	—	347,188
Net loss for the three months ended September 30, 2021	—	—	—	—	—	(6,133)	—	(6,133)
Cumulative translation adjustment	—	—	—	—	—	—	(2)	(2)
Balances as of September 30, 2021	**—**	**$ —**	**20,351,779**	**$ 204**	**$ 539,941**	**$ (384,184)**	**$ (197)**	**$ 155,764**
Balances as of June 30, 2020	161,041,754	$ 279,983	360,237	$ 4	$ 58,773	$ (345,047)	$ (210)	$ (286,480)
Exercise of stock options	—	—	175	—	—	—	—	—
Employee stock compensation	—	—	—	—	31	—	—	31
Issuance of Series G preferred stock, net of costs	62,500,000	49,783	—	—	—	—	—	—
Accretion of Series G issuance costs	—	217	—	—	(217)	—	—	(217)
Net loss for the three months ended September 30, 2020	—	—	—	—	—	(3,227)	—	(3,227)
Cumulative translation adjustment	—	—	—	—	—	—	14	14
Balances as of September 30, 2020	**223,541,754**	**$ 329,983**	**360,412**	**$ 4**	**$ 58,587**	**$ (348,274)**	**$ (196)**	**$ (289,879)**

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2020	223,541,754	$ 329,983	360,412	$ 4	$ 58,624	$ (351,676)	$ (190)	$ (293,238)
Exercise of stock options	—	—	11,783	—	10	—	—	10
Employee stock compensation	—	—	—	—	1,159	—	—	1,159
Issuance of common stock, net of offering costs	—	—	8,050,000	81	133,080	—	—	133,161
Reverse stock split	—	—	—	—	(1)	—	—	(1)
Conversion of Series G preferred stock	(223,541,754)	(329,983)	11,929,584	119	347,069	—	—	347,188
Net loss for the nine months ended September 30, 2021	—	—	—	—	—	(32,508)	—	(32,508)
Cumulative translation adjustment	—	—	—	—	—	—	(7)	(7)
Balances as of September 30, 2021	**—**	**$ —**	**20,351,779**	**$ 204**	**$ 539,941**	**$ (384,184)**	**$ (197)**	**$ 155,764**
Balances as of December 31, 2019	161,041,754	$ 279,983	483,931	$ 5	$ 58,708	$ (337,567)	$ (189)	$ (279,043)
Exercise of stock options	—	—	175	—	—	—	—	—
Repurchase of common stock	—	—	(123,694)	(1)	1	—	—	—
Employee stock compensation	—	—	—	—	95	—	—	95
Issuance of Series G preferred stock, net of costs	62,500,000	49,783	—	—	—	—	—	—
Accretion of Series G issuance costs	—	217	—	—	(217)	—	—	(217)
Net loss for the nine months ended September 30, 2020	—	—	—	—	—	(10,707)	—	(10,707)
Cumulative translation adjustment	—	—	—	—	—	—	(7)	(7)
Balances as of September 30, 2020	**223,541,754**	**$ 329,983**	**360,412**	**$ 4**	**$ 58,587**	**$ (348,274)**	**$ (196)**	**$ (289,879)**

The accompanying notes are an integral part of these condensed consolidated financial statements.

CVRx, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (32,508)	$ (10,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,159	95
Depreciation of property and equipment	112	52
Amortization of deferred financing costs and loan discount	206	217
Changes in fair value of convertible preferred stock warrants	13,294	(387)
Changes in operating assets and liabilities:		
Accounts receivable	(2,140)	138
Inventory	(97)	(1,243)
Prepaid expenses and other current assets	(2,359)	(241)
Accounts payable	58	228
Accrued expenses	1,558	(164)
Net cash used in operating activities	(20,717)	(12,012)
Cash flows from investing activities:		
Purchase of property and equipment	(645)	(210)
Net cash used in investing activities	(645)	(210)
Cash flows from financing activities:		
Proceeds from the exercise of common stock options	10	—
Proceeds from issuance of Series G Preferred Stock, net of fees	—	49,783
Payments related to reverse stock split	(1)	—
Proceeds from the issuance of common stock, net of offering costs	133,161	—
Net cash provided by financing activities	133,170	49,783
Effect of currency exchange on cash and cash equivalents	(7)	(7)
Net change in cash and cash equivalents	111,801	37,554
Cash and cash equivalents at beginning of year	59,112	25,741
Cash and cash equivalents at end of period	$ 170,913	$ 63,295
Supplemental Information:		
Cash paid for interest	$ 1,522	$ 1,528
Cash paid for income taxes	1	10

The accompanying notes are an integral part of these condensed consolidated financial statements.

CVRx, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Business organization

CVRx, Inc. (the “Company”) was incorporated in Delaware and is headquartered in Minneapolis, Minnesota. The Company has developed and is marketing a medical device, BAROSTIM NEO, for heart failure (“HF”) and resistant hypertension. The Company is focused on the sale of its product in the U.S. and Europe.

Management expects that operating losses and negative cash flows from operations could continue in the foreseeable future. There is no assurance that the Company will generate sufficient product sales to produce positive earnings or cash flows.

2. Summary of significant accounting policies

Statement presentation and basis of consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) applicable to interim financial statements. In the Company’s opinion, the accompanying unaudited condensed consolidated financial statements reflect all adjustments necessary for a fair presentation of the Company’s statements of financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods are not necessarily indicative of results that may be expected for the fiscal year as a whole or any other future period.

The condensed consolidated financial statements include the accounts of CVRx, Inc., its wholly owned subsidiary, CVRx Switzerland LLC, and its sales branch in Italy. All intercompany balances and transactions have been eliminated in consolidation.

JOBS Act accounting election

The Company is an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As a result, the Company has elected to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies.

Use of estimates

Preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

Cash and cash equivalents

Cash and cash equivalents include highly liquid investments with an original maturity of three months or less. As of September 30, 2021 and December 31, 2020, cash equivalents consisted of money market funds, which are stated at cost and approximate fair value.

Inventory

Inventory is stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand and remaining shelf life to record a provision for excess and obsolete inventory when appropriate.

Revenue recognition

The Company sells its products primarily through a direct sales force and to a lesser extent through a combination of sales agents and independent distributors. The Company's revenue consists primarily of the sale of its BAROSTIM NEO, which consists of two implantable components: a pulse generator and a stimulation lead.

Under Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. The Company recognizes net revenue on product sales when the customer obtains control of the Company's product, which generally occurs at a point in time upon delivery based on the contractual shipping terms of a contract.

Recent accounting pronouncements

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-02, *Leases* ("Topic 842"). The purpose of Topic 842 is to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet, including those previously classified as operating leases under current U.S. GAAP and disclosing key information about leasing arrangements. Topic 842 is effective for private companies and smaller reporting companies for annual periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted, and the Company must elect whether the date of initial application is the beginning of the earliest comparative period presented in the financial statements, or the beginning of the period of adoption. While the Company is still in the process of determining the effect that the new standard will have on its financial position and results of operations, the Company expects to recognize additional assets and corresponding liabilities on its condensed consolidated balance sheets, as a result of its operating lease portfolio as disclosed in Note 10 — Commitments and Contingencies.

3. Selected balance sheet information

Inventory consists of the following at:

(in thousands)	September 30, 2021	December 31, 2020
Raw material	$ 1,083	$ 1,361
Work-in-process	287	321
Finished goods	2,070	1,661
	$ 3,440	$ 3,343

Property and equipment, net consists of the following at:

(in thousands)	September 30, 2021	December 31, 2020
Office furniture and equipment	$ 271	$ 189
Lab equipment	1,440	1,272
Computer equipment and software	516	516
Leasehold improvements	45	44
Capital equipment in process	483	89
	2,755	2,110
Less: Accumulated depreciation and amortization	1,812	1,700
	$ 943	$ 410

Depreciation expense was $42,000 and $17,000 for the three months ended September 30, 2021 and 2020, respectively, and $112,000 and $52,000 for the nine months ended September 30, 2021 and 2020, respectively.

Accrued expenses consist of the following at:

(in thousands)	September 30, 2021	December 31, 2020
Clinical trial and other professional fees	$ 1,638	$ 1,690
Bonuses	1,628	794
Paid time off	723	552
Interest payable	451	356
Other	537	191
	$ 4,977	$ 3,583

4. Fair value measurements

Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level 1 — Inputs are quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and inputs (other than quoted prices) that are observable for the asset or liability, either directly or indirectly.
- Level 3 — Inputs are unobservable for the asset or liability.

The following table sets forth the Company's liabilities that were measured at fair value on a recurring basis by level within the fair value hierarchy:

(in thousands)

Balance as of December 31, 2020	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred stock warrant liability	$ —	$ —	$ 3,911	$ 3,911
Total liabilities	$ —	$ —	$ 3,911	$ 3,911

The convertible preferred stock warrant liability related to warrants issued in connection with loan and security agreements entered into in September 2014, as amended in July 2015, in May 2016 and in September 2019. These warrants were originally issued to purchase shares of Series F-2 convertible preferred stock and Series G convertible preferred stock ("Series G Preferred Shares"). In connection with the closing of the initial public offering ("IPO"), these convertible preferred stock warrants became warrants to purchase 108,406 shares of common stock and were reclassified to equity.

The convertible preferred stock warrant liability also related to a warrant issued to Biosense Webster, Inc. ("BWI"), an affiliate of Johnson & Johnson Innovation — JJDC, Inc., to purchase Series G Preferred Shares with an exercise price of $0.01 per share. In connection with the closing of the IPO, the BWI warrant to purchase Series G Preferred Shares became exercisable to purchase 607,725 shares of common stock at an exercise price of $0.16 per share.

The Company's recurring fair value measurements using significant unobservable inputs (Level 3) related solely to the Company's convertible preferred stock warrant liability. The convertible preferred stock warrant liability was remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. In connection with the closing of the IPO, all of the outstanding convertible preferred stock warrants were converted to common stock warrants. The related liability was remeasured at the time of the IPO and reclassed to additional paid-in capital.

The fair value of the convertible preferred stock warrant liability was determined using the Black-Scholes option pricing model with the following inputs during the nine months ended:

The following table sets forth a summary of changes in the estimated fair value of the Company's convertible preferred stock warrants during the nine months ended:

	September 30,	
(in thousands)	**2021**	**2020**
Beginning of the period	$ 3,911	$ 3,540
Change in fair value	13,294	(17)
Conversion to common stock warrants	(17,205)	—
End of the period	$ —	$ 3,523

There were no transfers in or out of Level 1, Level 2 or Level 3 fair value measurements during the periods ended September 30, 2021 and December 31, 2020.

5. Debt

Horizon loan agreement

In September 2019, the Company entered into a loan and security agreement ("Horizon loan agreement") with Horizon Technology Finance Corporation ("Horizon") under which it could borrow up to a total of $20.0 million at a floating per annum rate equal to 10% plus the amount by which the 30-day U.S. dollar LIBOR rate on the first business day of the month exceeds 2.2%. The Horizon loan agreement initially required interest only payments through October 2021 and then 36 monthly principal and interest payments beginning in November 2021. A final payment of $0.7 million, equal to 3.5% of the original principal, is due in October 2024. The Horizon loan agreement initially required the Company to maintain cash on deposit of not less than $5.0 million in accounts over which Horizon maintained an account control agreement. This minimum cash on deposit requirement was released in July 2020, following the satisfaction of a financing milestone. The borrowings are collateralized by all or substantially all of the assets of the Company. The Horizon loan agreement requires the payment of certain penalties if the loan is paid off prior to maturity for any reason, including pursuant to a subjective acceleration clause, and includes various restrictive covenants, including a restriction on the payment of dividends. The Company was in compliance with these covenants as of September 30, 2021.

In August 2020, the Company entered into an amended agreement with Horizon to extend the interest only period through April 2022, followed by 30 monthly principal and interest payments beginning in May 2022.

In connection with the Horizon loan agreement, the Company recorded $1.1 million of debt issuance costs and discounts as a reduction of long-term debt. Of this total, $0.5 million related to legal fees and an investment bank fee and $0.6 million related to the warrants to purchase Series G Preferred Shares issued by the Company. These warrants were exercisable on the grant date at a price of $0.80 per share and expire in September 2029. The Company used the Black-Scholes option pricing model to determine the grant date fair value of these warrants.

The annual principal maturities of debt as of September 30, 2021 are as follows (in thousands):

2021	$ —
2022	5,333
2023	8,000
2024	6,667
	20,000
Less: Unamortized debt costs and discounts	(516)
Less: current portion	(3,333)
Long-term debt	$ 16,151

6. Stockholders' equity

Initial Public Offering

During 2016, the Company issued 72,125,000 shares of Series G Preferred Shares at a price of $0.80 per share, for net proceeds to the Company of approximately $57.4 million after deducting offering expenses payable by the Company. The same Series G investors agreed to purchase an additional $35.3 million of Series G Preferred Shares upon the Company's achievement of a certain operational milestone, subject to limited closing conditions. In January 2019, May 2019, and August 2019, the Series G investors purchased additional Series G Preferred Shares, resulting in net proceeds to the Company of $24.7 million.

In July of 2020, the Company issued 62,500,000 additional Series G Preferred Shares, at a price of $0.80 per share, for net proceeds to the Company of $49.8 million after deducting offering expenses payable by the Company.

On May 31, 2016, holders of the requisite number of the Company's then-outstanding convertible preferred stock approved the conversion of all preferred stock into shares of the Company's common stock in connection with a new equity financing. Accordingly, all of the Company's then-outstanding preferred stock was converted on a one-for-one basis into shares of the Company's common stock. Under the terms of the equity financing, each prior holder of preferred stock who purchased a required amount of securities in the new financing was entitled to exchange certain of the shares of common stock received in the conversion described above into new prime series of preferred stock corresponding to the series of preferred stock from which the common stock was previously converted. All of the previously held Series A-1, B-1, C-1, D-1, E-1 and F preferred stock had similar features as the Series A-2 preferred stock ("Series A-2 Preferred Shares"), Series B-2 preferred stock ("Series B-2 Preferred Shares"), Series C-2 preferred stock ("Series C-2 Preferred Shares"), Series D-2 preferred stock ("Series D-2 Preferred Shares"), Series E-2 preferred stock ("Series E-2 Preferred Shares"), and Series F-2 preferred stock ("Series F-2 Preferred Shares") described below. The Series A-2, Series B-2, Series C-2, Series D-2, Series E-2, Series F-2 and Series G Preferred Shares are referred to collectively as the "Preferred Shares."

On July 2, 2021, the Company closed its IPO of 8,050,000 shares of its common stock at a public offering price of $18.00 per share, which included 1,050,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares, for net proceeds from the IPO, after

deducting the underwriting discount and other offering expenses payable by the Company totaling $1.6 million, of $133.2 million.

Upon the closing of the IPO, all shares of convertible preferred stock were automatically converted into common stock. Series G Preferred Shares were converted into common stock on a 15.819-for-1 basis, and all other shares of convertible preferred stock were automatically converted into common stock on a 39.548-for-1 basis. The conversion of the outstanding preferred stock resulted in an aggregate of 11,929,584 shares of common stock.

Reverse Stock Split

In connection with the IPO, the Company's Board of Directors and stockholders approved a 1-for-39.548 reverse stock split of the Company's common stock. The reverse stock split became effective on June 22, 2021. The par value of the common stock was not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the convertible preferred stock will convert into common stock in connection with the closing of the IPO. Accordingly, all share and per-share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and the adjustment of the conversion ratio of the convertible preferred stock.

Common Stock Warrants

In connection with the IPO, the warrants to purchase shares of convertible preferred stock automatically converted into warrants to purchase common stock, resulting in the reclassification of the related convertible preferred stock warrant liability to additional paid-in capital. Upon the closing of the IPO these warrants to purchase convertible preferred stock became exercisable for 716,131 shares of common stock upon conversion at a weighted average exercise price of $2.39 per share.

7. Stock-Based compensation

Summary of plans and activity

In June 2001, the Company's Board of Directors and stockholders established the 2001 Stock Incentive Award Plan ("2001 Plan"). Under the 2001 Plan, as amended, 2,674,749 shares of common stock had been reserved for the issuance of incentive stock options granted to employees, nonemployee directors, consultants or independent contractors. Options granted under the 2001 Plan have vesting terms that range from the day of grant to four years and expire within a maximum term of 10 years from the grant date.

In connection with the IPO in 2021, the Company's Board of Directors and stockholders established the 2021 Equity Incentive Plan ("2021 Plan"). The number of shares of common stock initially reserved for issuance under the 2021 Plan was 1,854,490 newly reserved shares in addition to the 600,373 shares that remained available for issuance under the 2001 Plan. The shares available for issuance under the 2021 Plan will automatically increase on the first day of each year, commencing January 1, 2022 and ending on (and including) January 1, 2031, in an amount equal to 5% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of each automatic increase, or such lesser number of shares as determined by the Board of Directors. The 2021 Plan provides for the issuance of stock options, stock appreciation rights, restricted stock awards, stock unit awards and other stock-based awards and cash incentive awards to employees, consultants and non-employee directors of the Company and its subsidiaries. Awards granted under the 2021 Plan will have such vesting schedules and other terms as determined by the Compensation Committee and stock options and stock appreciation rights have a maximum term of 10 years from the grant date. No further awards can be made under the 2001 Plan following the adoption of the 2021 Plan. As of September 30, 2021, there were 1,791,888 shares available for future issuance under the 2021 Plan.

Options are granted at exercise prices not less than the fair market value (as determined by the Board of Directors) of the Company's common stock on the date of grant.

During the years 2008 through September 30, 2021, the Board of Directors authorized the grant of stock options for the purchase of shares of common stock to the employers of certain nonemployee directors. The options were not granted under the 2001 Plan or the 2021 Plan, but terms are substantially the same as the Company's standard form of option agreement for nonemployee directors as they have an exercise price not less than the fair market value on the grant date and vest over 48 months from the date of grant.

The following is a summary of stock option activity:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
			(in thousands)
Balance as of December 31, 2020	1,473,359	$ 2.64	
Granted	1,238,426	13.00	
Cancelled / Forfeited	(42,669)	10.31	
Exercised	(11,783)	0.88	
Balance as of September 30, 2021	2,657,333	$ 7.35	$ 25,475
Options exercisable as of September 30, 2021	1,009,785	$ 2.36	$ 14,330

As of September 30, 2021, stock options outstanding included 9,993 options that were not granted under the 2001 Plan or the 2021 Plan. For options outstanding as of September 30, 2021, the weighted average remaining contractual life was 8.4 years. For options exercisable as of September 30, 2021, the weighted average remaining contractual life was 7.3 years.

In connection with the IPO, the Company's Board of Directors and stockholders also established an Employee Stock Purchase Plan (the "ESPP"). The number of shares of common stock initially reserved for issuance under the ESPP was 278,170. The shares available for issuance under the ESPP will automatically increase on the first day of each year, commencing January 1, 2022 and ending on (and including) January 1, 2031, in an amount equal to 1% of the total number of shares of the Company's common stock outstanding on the last day of the calendar month before the date of each automatic increase, or such lesser number of shares as determined by the Board of Directors. The ESPP will permit certain of the Company's U.S. employees to purchase shares of the Company's common stock at a price per share not less than 85% of the lower of (i) the closing market price per share of the Company's common stock on the first day of the applicable purchase period or (ii) the closing market price per share of the Company's common stock on the purchase date at the end of the applicable six-month purchase period. The Company expects the first purchase period to commence in 2022. Accordingly, as of September 30, 2021, no shares of common stock have been purchased under the ESPP.

Stock-based compensation expense

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options on the grant date. The Company measures stock-based compensation expense based on the grant date fair value of the award and recognizes compensation expense over the requisite service period, which is generally the vesting period. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. The Company estimates pre-vesting forfeitures at the time of grant by analyzing historical data and revises those estimates in subsequent periods if actual forfeitures differ from those estimates.

The following table provides the weighted average fair value of options granted to employees and the related assumptions used in the Black-Scholes option pricing model for the nine months ended September 30, 2021. No options were issued during the nine months ended September 30, 2020.

	September 30, 2021
Weighted average fair value of options granted	$ 5.25
Expected term (in years) — non-officer employees	2.7 to 6.1
Expected term (in years) — officer employees	3.0
Expected volatility	56.1% to 63.4 %
Expected dividend yield	— %
Risk-free interest rate	0.17% to 0.47 %

The Company reviews these assumptions on a periodic basis and adjusts them, as necessary. The expected term of an award was determined based on the Company's analysis of historical exercise behavior while taking into consideration various participant demographics and option characteristics. We utilize the simplified method to develop the estimate of the expected term. The expected volatility is based upon observed volatility of comparable public companies. The expected dividend yield is assumed to be zero, as the Company has never paid dividends and has no current plans to do so. The risk-free interest rate is based on the yield on U.S. Treasury securities for a period approximating the expected term of the options being valued.

For the three and nine months ended September 30, 2021 and 2020, the Company recognized stock-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2021	2020	2021	2020
Selling, general & administrative	$ 353	$ 20	$ 830	$ 62
Research & development	115	11	319	32
Cost of goods sold	6	—	10	1
	$ 474	$ 31	$ 1,159	$ 95

As of September 30, 2021, unrecognized compensation expense related to unvested stock-based compensation arrangements was $6.3 million. As of September 30, 2021, the related weighted average period over which it is expected to be recognized is approximately 3.5 years.

Performance-Based options

As of September 30, 2021, the Company had 10,493 stock options outstanding that contained vesting conditions contingent on the achievement of certain milestones. Assuming continued service by the employees, the options would start vesting over a 48-month period upon achievement of the performance criteria. As of September 30, 2021, the Company determined that the likelihood of achieving the milestones was not probable and therefore no stock-based compensation expense was recorded.

Early exercise of stock options

Under the 2001 Plan, the Company has issued options to certain executive officers with early-exercise provisions. The options may be exercised by the holder any time after they are granted. The Company has the right to repurchase, at the original option exercise price, shares issued pursuant to such early-exercise provisions, upon the termination of employment or death of the stockholder. This repurchase right expires based upon the original option vesting schedule. As of September 30, 2021 and 2020, there have been no early exercises and therefore there is no liability recorded for the early exercise of stock options.

8. Income taxes

As of both September 30, 2021 and 2020, a valuation allowance was recorded against all deferred tax assets due to the Company's cumulative net loss position. Provision for income taxes for the three months ended September 30, 2021 and 2020 was $23,000 and $19,000, respectively. Provision for income taxes for the nine months ended September 30, 2021 and 2020 was $66,000 and $64,000, respectively.

As of December 31, 2020, the Company had federal and state net operating loss carryforwards ("NOLs") of approximately $296.1 million and $88.0 million, respectively. The federal NOLs begin to expire in 2021 and the state NOLs began expiring in 2020. As of December 31, 2020, the Company had federal and state tax credit carryforwards of approximately $8.6 million and $1.5 million, respectively. The federal and state tax credit carryforwards begin to expire in 2021 and 2028, respectively.

Utilization of net operating loss carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of ownership would limit the Company's utilization of the net operating losses and could be triggered by subsequent sales of securities by the Company or its stockholders.

9. (Loss) Earnings Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (6,133)	$ (3,227)	$ (32,508)	$ (10,707)
Accretion of preferred stock to redemption value	—	(217)	—	(217)
Net loss attributable to common stockholders	$ (6,133)	$ (3,444)	$ (32,508)	$ (10,924)
Denominator:				
Weighted average common shares outstanding — basic and diluted	20,126,672	360,356	6,975,386	396,071
Net loss per share attributable to common stockholders — basic and diluted	$ (0.30)	$ (9.56)	$ (4.66)	$ (27.58)

The Company's potentially dilutive securities, which include stock options, shares of convertible preferred stock, warrants to purchase shares of convertible preferred stock and warrants to purchase shares of common stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders, as the effect would be to reduce the net loss per share attributable to common stockholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2021	2020
Options to purchase common stock	2,657,333	961,885
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	—	108,406
Warrants to purchase common stock	716,131	—
Redeemable convertible preferred stock (as converted to common stock)	—	11,929,584
	3,373,464	12,999,875

10. Commitments and contingencies

Commitments

Operating Leases

The Company has entered into an operating lease agreement for its office, manufacturing and research facility, which expires in 2024. Rent expense for the three months ended September 30, 2021 and 2020 was $91,000 and $90,000, respectively. Rent expense for the nine months ended September 30, 2021 and 2020 was $279,000 and $276,000, respectively.

Future minimum lease payments under all operating leases as of September 30, 2021, are as follows for the years ending (in thousands):

December 31, 2021	$ 56
December 31, 2022	227
December 31, 2023	234
December 31, 2024	138
	$ 655

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual or disclosure as of September 30, 2021 or December 31, 2020.

11. Employee benefit plans

The Company sponsors a voluntary defined-contribution employee retirement plan (the “401(k) plan”) for its U.S. employees. The 401(k) plan provides that each participant may contribute pre-tax or post-tax compensation up to the statutory limit allowable. Under the 401(k) plan, each participant is fully vested in his or her deferred salary contributions when contributed. The Company does not provide matching contributions to employees.

12. Segment, geographic information and revenue disaggregation

The chief operating decision maker for the Company is the Chief Executive Officer. The Chief Executive Officer reviews financial information presented on a consolidated basis, accompanied by information about revenue by geographic region, for purposes of allocating resources and evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results or plans for levels or components below the consolidated unit level. Accordingly, the Company has determined that it has a single reportable and operating segment structure. The Company and its Chief Executive Officer evaluate performance based primarily on revenue in the geographic locations in which the Company operates.

The Company derives all its revenues from sales to customers in Europe and the U.S. The following table provides revenue by country for each location accounting for more than 10% of the total revenue for the three and nine months ended (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
U.S.	$ 2,572	$ 296	$ 6,289	$ 902
Germany	682	579	2,589	2,657
Other countries	141	122	500	406
	$ 3,395	$ 997	$ 9,378	$ 3,965

As September 30, 2021 and 2020, long-lived assets were located primarily in the U.S.

13. Subsequent events

On November 3, 2021 the Company fully repaid all amounts outstanding under the $20.0 million principal amount Horizon loan agreement. The total repayment amount was $21.3 million, inclusive of prepayment and other fees, and will be reflected within the Company's financial statements for the fiscal year ended December 31, 2021.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are a commercial-stage medical device company focused on developing, manufacturing and commercializing innovative and minimally invasive neuromodulation solutions for patients with cardiovascular disease. Our proprietary platform technology, BAROSTIM, is designed to leverage the power of the brain and nervous system to address the imbalance of the Autonomic Nervous System, which causes HF with reduced Ejection Fraction ("HFrEF") and other cardiovascular diseases. Our second-generation product, BAROSTIM NEO, is the first and only commercially available neuromodulation device indicated to improve symptoms for patients with HFrEF. BAROSTIM NEO provides Baroreflex Activation Therapy by sending imperceptible and persistent electrical pulses to baroreceptors located in the wall of the carotid artery to signal the brain to modulate cardiovascular function. BAROSTIM NEO is currently approved by the U.S. Food and Drug Administration ("FDA") to improve the symptoms of patients with HFrEF and is CE Marked for HFrEF and resistant hypertension.

Since our inception we have generated minimal revenue, as our activities have consisted primarily of developing our BAROSTIM Therapy, conducting our BeAT-HF pre-market and post-market pivotal studies in the U.S. and filing for regulatory approvals. Our ability to generate revenue from product sales and become profitable will depend on our ability to successfully commercialize BAROSTIM NEO and any product enhancements we may advance in the future. We expect to derive future revenue by expanding our own dedicated salesforce and increasing awareness of our BAROSTIM NEO among payors, physicians and patients.

Our sales and marketing efforts are directed at electrophysiologists, HF specialists, general cardiologists and vascular surgeons because they are the primary users of our technology. However, we consider the hospitals, where the procedures are performed primarily in an outpatient setting, to be our customers, as they are the purchasing entities of our BAROSTIM NEO in the U.S. We intend to continue making significant investments building our U.S. commercial infrastructure by expanding and training our U.S. sales force. We have dedicated significant resources to educate physicians who treat HFrEF about the advantages of BAROSTIM NEO and train them on the implant procedure.

The costs for the device and implantation procedure are reimbursed through various third-party payors, such as government agencies and commercial payors. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for BAROSTIM NEO. As a result, we have prioritized coverage by the Centers for Medicare and Medicaid Services ("CMS") while simultaneously developing processes to engage commercial payors. As of July 2020, all Medicare Administrative Contractors have retired automatic coverage denial policies for our Current Procedural Terminology ("CPT") codes, thereby allowing hospitals to be paid for the BAROSTIM procedure. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to assist patients and physicians in obtaining appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist. Outside the U.S., reimbursement levels vary by country and within some countries by region. BAROSTIM NEO is eligible for reimbursement in certain countries in the European Union ("EU"), such as Germany, where annual healthcare budgets for the hospital generally determine the number of patients to be treated and the prices to be paid for the related devices that may be purchased.

We manage all aspects of manufacturing operations and product supply of our BAROSTIM NEO, which includes final assembly, testing and packaging of our implantable pulse generator ("IPG") and stimulation lead, at our headquarters in Minneapolis, Minnesota. We utilize components or various subassemblies manufactured by third-party suppliers, some of which have significant lead times. Many of these components are from a limited number of suppliers. We believe that our component manufacturers are recognized in their field for their competency to manufacture the respective portions of our BAROSTIM NEO and have quality systems established that meet FDA requirements. We seek to maintain higher levels of inventory to protect ourselves from supply interruptions and continue to seek to broaden and strengthen our supply chain through additional sourcing channels.

From our inception until the IPO, we financed our operations primarily through preferred stock financings, and additionally, from sales of our BAROSTIM products and amounts borrowed under our current and past credit facilities. We have devoted substantially all of our resources to research and development activities related to our BAROSTIM Therapy, including clinical and regulatory initiatives to obtain marketing approval, and sales and marketing activities.

We intend to use a portion of the IPO proceeds to continue funding the expansion of our direct sales force and commercial organization related to BAROSTIM NEO in the U.S. We also intend to continue investing in research and development in the near term to improve clinical outcomes, optimize patient adoption and comfort, increase patient access and enhance the physician and patient experience. Longer term, we plan to explore BAROSTIM NEO's potential to expand its indications for use to other cardiovascular diseases. As a result of these investments and our commercialization efforts, we expect to continue to incur net losses for the next several years, which may require additional funding and could include future equity and debt financings.

Recent developments

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus ("COVID-19") has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have been significant and governments around the world, including in the U.S., have implemented severe travel restrictions, social distancing requirements, quarantines, stay-at-home orders and other significant restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge and is affecting hospitals, physicians, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. and world economy and in financial markets.

The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by decreasing and delaying procedures performed to implant our BAROSTIM NEO, and we expect the pandemic will continue to negatively impact our business, financial condition and results of operations. Beginning in March 2020, our revenue was negatively impacted by COVID-19 as healthcare facilities and

clinics began restricting in-person access to their clinicians, reducing patient consultations and treatments or temporarily closing their facilities. As a result, substantially all of our then-scheduled procedures were postponed, and numerous other cases could not be scheduled. During May 2020, the widespread shutdown resulted in key physician-society conferences being moved to a virtual setting, which directly impacted our planned commercial launch in the U.S.

In response to the COVID-19 pandemic, we have implemented a variety of measures intended to help us manage its impact while maintaining business continuity to support our customers and patients. These measures include:

- Establishing safety protocols, facility enhancements, and work-from-home strategies to protect our employees;
- Ensuring that our manufacturing and supply chain operations remain intact and operational;
- Keeping our workforce intact, including our experienced and specialized U.S. sales and clinical support team;
- Implementing virtual physician education programs to support opening new accounts with minimal in person interaction; and
- Increasing our capital resources through the issuance of shares of Series G Preferred Shares for net proceeds of $49.8 million in July 2020.

Our hospital customers in the U.S. and Europe began to gradually perform elective procedures again during the fourth quarter of 2020. We believe the recovery of our business in the fourth quarter of 2020 and through the first nine months of 2021 is an encouraging sign for when remaining shelter-in-place and hospital limitations are lifted. As the pandemic has eased, we are experiencing the following positive trends:

- Strong physician participation in our virtual educational events;
- Expansion into new accounts; and
- Hospitals accepting patients for elective procedures at closer to pre-pandemic levels in the U.S.

Despite the encouraging signs of recovery of our business, we believe the challenges resulting from COVID-19 will likely continue for the duration of the pandemic. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and spread of COVID-19 and its variants and the actions to contain the spread of COVID-19 and its variants or treat its impact.

Factors affecting our performance

We believe there are several important factors that have impacted and that we expect will continue to impact our business and results of operations. These factors include:

- Growing and supporting our U.S. commercial organization;
- Promoting awareness among physicians, hospitals and patients to accelerate adoption of our BAROSTIM NEO;
- Raising awareness among payors to build upon reimbursement for BAROSTIM NEO;

- Investing in research and development to foster innovation and further simplify our BAROSTIM NEO procedure; and

- Leveraging our manufacturing capacity to further improve our gross margins.

Components of results of operations

Revenue

We have derived primarily all of our historical revenue from the sale of our BAROSTIM NEO to hospitals in Germany and other select countries in Europe. Revenue from sales of our BAROSTIM NEO in Europe fluctuates based on the average selling price of our BAROSTIM NEO as determined by location of sale and channel mix, each of which may vary significantly from country to country. Our revenue from international sales can also be significantly impacted by fluctuations in foreign currency exchange rates.

Our U.S. sales have increased since the pre-market approval of our BAROSTIM NEO by the FDA in August 2019, and the subsequent reimbursement changes in 2020. We expect to continue to drive increases in revenue through our efforts to increase awareness of BAROSTIM NEO among physicians, patients and payors and by the expansion of our U.S. sales force. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

Cost of goods sold and gross margin

Cost of goods sold consists primarily of acquisition costs of the components and subassemblies of BAROSTIM NEO, allocated manufacturing overhead, and scrap and inventory obsolescence, as well as distribution-related expenses such as logistics and shipping costs. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our revenue grows. Gross margin may also vary based on regional differences in rebates and incentives negotiated with certain customers.

We calculate gross margin as revenue less cost of goods sold divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, but is primarily driven by the average sale price of our product, the percentage of products sold that include a full system (i.e., an IPG and a stimulation lead), as compared to individual IPG sales, and the allocated manufacturing overhead. Although we sell the majority of our devices directly to hospitals, the impact of the average selling price on gross margin is driven by the percentage of products we sold to distributors as compared to those sold directly to hospitals as our average selling price is typically higher on products we sell directly. The full system sales typically have a lower gross margin as they include the cost of an IPG and a stimulation lead whereas individual IPG sales only include the cost of an IPG. The manufacturing overhead costs of BAROSTIM NEO are directly aligned to our production volume and therefore the cost per product is reduced if production levels increase. While we expect our gross margin to be positively affected over time to the extent we are successful in selling more product through our direct sales force and by increasing our production volumes, it will likely fluctuate from period to period as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

Research and development (“R&D”) expenses consist primarily of personnel costs, including salaries, bonuses, employee benefits and stock-based compensation expenses for our R&D employees. R&D expenses also include costs associated with product design efforts, development prototypes, testing, clinical trial programs and regulatory activities, contractors and consultants, equipment and software to support our development, facilities and information technology. We expense research and development costs as they are incurred. We expect R&D expenses to increase in absolute dollars as we continue to develop enhancements to BAROSTIM NEO. Our R&D expenses may fluctuate from period to period due to the timing and extent of our product development and clinical trial expenses related to BAROSTIM NEO in HFrEF.

Selling, general and administrative expenses

Selling, general and administrative ("SG&A") expenses consist primarily of personnel costs, including base salaries, bonuses, employee benefits and stock-based compensation expense for our sales and marketing personnel, including sales commissions, and for administrative personnel that support our general operations such as executive management, financial accounting, information technology, and human resources personnel. SG&A expenses also include costs attributable to marketing, as well as travel, legal fees, financial audit fees, insurance, fees for other consulting services, depreciation and facilities. We expense commissions at the time of the sale.

We expect SG&A expenses to increase in absolute dollars as we continue to expand our direct sales force and commercial organization in the U.S. In addition, we will continue to increase our international presence and to develop and assist our channel partners. We also expect our administrative expenses will increase as we increase our headcount and information technology to support our operations as a public company. Additionally, we anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company. However, we expect our SG&A expenses to decrease as a percentage of revenue as our revenue grows.

Interest expense

Interest expense consists of interest on our debt and amortization of associated debt discount.

Other income (expense), net

Other income (expense), net consists primarily of the fair value adjustments related to our outstanding convertible preferred stock warrants, which are accounted for as a liability and marked-to-market at each reporting period. The final fair value adjustment of the warrant liability was recorded upon the closing of the IPO in connection with the conversion of the warrants to common stock warrants. Other items include gains (losses) on the extinguishment of debt, interest income earned on our cash and cash equivalents, and the effect of exchange rates on our foreign currency-denominated asset and liability balances. Translation adjustments are recorded as foreign currency gains (losses) in the condensed consolidated statements of operations and comprehensive loss.

Provision for income taxes

Provision for income taxes consists primarily of income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including NOL carryforwards, R&D credits and other tax credits.

Results of operations

Consolidated results of operations for the three months ended September 30, 2021, compared to the three months ended September 30, 2020

(unaudited and in thousands)	Three months ended September 30, 2021	2020	Change $	Change %
Revenue	$ 3,395	$ 997	$ 2,398	241 %
Cost of goods sold	876	212	664	313 %
Gross profit	2,519	785	1,734	221 %
Gross margin	74 %	79 %		
Operating Expenses:				
Research and development	1,699	1,500	199	13 %
Selling, general and administrative	8,111	2,327	5,784	249 %
Total operating expenses	9,810	3,827	5,983	156 %
Loss from operations	(7,291)	(3,042)	(4,249)	140 %
Interest expense	(614)	(621)	7	(1)%
Other income, net	1,795	455	1,340	295 %
Loss before income taxes	(6,110)	(3,208)	(2,902)	90 %
Provision for income taxes	(23)	(19)	(4)	21 %
Net loss	$ (6,133)	$ (3,227)	$ (2,906)	90 %

NM – Not meaningful

Revenue

	Revenue by Geography			
	Three months ended September 30,		Change	
(unaudited and in thousands)	2021	2020	$	%
United States	$ 2,572	$ 296	$ 2,276	769 %
Europe	823	701	122	17 %
Total Revenue	$ 3,395	$ 997	$ 2,398	241 %

Total revenue increased by $2.4 million, or 241%, to $3.4 million for the three months ended September 30, 2021, compared to the three months ended September 30, 2020.

Revenue generated in the U.S. was $2.6 million for the three months ended September 30, 2021, an increase of $2.3 million, or 769%, over the three months ended September 30, 2020. HF revenue units in the U.S. totaled 84 and four for the three months ended September 30, 2021 and 2020, respectively. HF revenue in the U.S. totaled $2.5 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively. The increase was primarily driven by continued growth following the U.S. HF commercial launch in 2020, which resulted in the expansion into new sales territories and increased physician and patient awareness of our BAROSTIM NEO. As of September 30, 2021, we had a total of 38 active implanting centers, as compared to four as of September 30, 2020. Active implanting centers are customers that have completed at least one commercial HF implant in the last 12 months. The number of sales territories in the U.S. increased by three to a total of 11 during the three months ended September 30, 2021. Legacy hypertension revenue in the U.S. totaled $0.1 million and $0.2 million for the three months ended September 30, 2021 and 2020, respectively.

Revenue generated in Europe was $0.8 million for the three months ended September 30, 2021, an increase of $0.1 million, or 17%, over the three months ended September 30, 2020. Total revenue units in Europe for the three months ended September 30, 2021 increased to 38 from 32 for the three months ended September 30, 2020. The slight revenue increase was primarily due to the lessening impact of the COVID-19 pandemic in Germany. The number of sales territories in Europe remained consistent at six during the three months ended September 30, 2021.

Cost of goods sold and gross margin

Cost of goods sold increased $0.7 million, or 313%, to $0.9 million for the three months ended September 30, 2021, compared to the three months ended September 30, 2020. This increase was primarily due to higher sales of our BAROSTIM NEO.

Gross margin decreased to 74% for the three months ended September 30, 2021, compared to 79% for the three months ended September 30, 2020. Gross margin for the three months ended September 30, 2021 was lower due to a larger percentage of our revenue units coming from full systems, which require an IPG and a stimulation lead, as compared to individual IPG sales. This was partially offset by an increase in the average selling price.

Research and development expenses

R&D expenses increased $0.2 million, or 13%, to $1.7 million for the three months ended September 30, 2021, compared to the three months ended September 30, 2020. This change was primarily due to an increase of $0.1 million in non-cash stock-based compensation expense and an increase of $0.1 million in compensation expenses, including salaries and other employee-related expenses, mainly as a result of increased headcount.

Selling, general and administrative expenses

SG&A expenses increased $5.8 million, or 249%, to $8.1 million for the three months ended September 30, 2021, compared to the three months ended September 30, 2020. This was primarily driven by an increase of $2.8 million in compensation expenses, including salaries and commissions, and other employee-related expenses, mainly as a result of increased headcount, a $0.8 million increase in marketing and advertising expenses primarily related to the commercialization of our BAROSTIM NEO in the U.S., a $0.7 million increase in insurance costs incurred as a result of the IPO, $0.4 million of additional travel expenses, a $0.3 million increase in non-cash stock-based compensation expense, and a $0.3 million increase in consulting expenses.

Interest expense

Interest expense remained consistent at $0.6 million for each of the three months ended September 30, 2021 and 2020.

Other income, net

Other income, net was $1.8 million for the three months ended September 30, 2021, compared to $0.5 million for the three months ended September 30, 2020, driven by a $1.5 million increase in income related to the decrease in fair value of our convertible preferred stock warrants due to the change in our common stock price from June 30, 2021 to July 2, 2021, which is the date the warrants converted to common stock warrants.

Provision for income taxes

Provision for income taxes was nominal for each of the three months ended September 30, 2021 and September 30, 2020.

Consolidated results of operations for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020

(unaudited and in thousands)	Nine months ended September 30, 2021	Nine months ended September 30, 2020	Change $	Change %
Revenue	$ 9,378	$ 3,965	$ 5,413	137 %
Cost of goods sold	2,656	989	1,667	169 %
Gross profit	6,722	2,976	3,746	126 %
Gross margin	72 %	75 %		
Operating Expenses:				
Research and development	5,704	5,900	(196)	(3)%
Selling, general and administrative	18,198	6,455	11,743	182 %
Total operating expenses	23,902	12,355	11,547	93 %
Loss from operations	(17,180)	(9,379)	(7,801)	83 %
Interest expense	(1,823)	(1,856)	33	(2)%
Other (expense) income, net	(13,439)	592	(14,031)	NM
Loss before income taxes	(32,442)	(10,643)	(21,799)	205 %
Provision for income taxes	(66)	(64)	(2)	3 %
Net loss	$ (32,508)	$ (10,707)	$ (21,801)	204 %

NM – Not meaningful

Revenue

(unaudited and in thousands)	Revenue by Geography Nine months ended September 30, 2021	Revenue by Geography Nine months ended September 30, 2020	Change $	Change %
United States	$ 6,289	$ 902	$ 5,387	597 %
Europe	3,089	3,063	26	1 %
Total Revenue	$ 9,378	$ 3,965	$ 5,413	137 %

Revenue increased by $5.4 million, or 137%, to $9.4 million for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Revenue generated in the U.S. was $6.3 million for the nine months ended September 30, 2021, an increase of $5.4 million, or 597%, over the nine months ended September 30, 2020. Total HF revenue units in the U.S. totaled 195 and 11 for the nine months ended September 30, 2021 and 2020, respectively. HF revenue in the U.S. totaled $5.7 million and $0.4 million for the nine months ended September 30, 2021 and 2020, respectively. The increase was primarily driven by the continued growth following the commercial launch in 2020, which resulted in the expansion into new sales territories and increased physician and patient awareness of our BAROSTIM NEO. The number of sales territories in the U.S. increased by five to a total of 11 during the nine months ended September 30, 2021. Legacy hypertension revenue in the U.S. totaled $0.6 million and $0.5 million for the nine months ended September 30, 2021 and 2020, respectively.

Revenue generated in Europe was $3.1 million for the nine months ended September 30, 2021, a slight increase of $26,000, or 1%, over the nine months ended September 30, 2020. Total revenue units in Europe decreased to 137 from 138 for the nine months ended September 30, 2021 and 2020, respectively. The number of sales territories in Europe remained consistent at six during the nine months ended September 30, 2021.

Cost of goods sold and gross margin

Cost of goods sold increased $1.7 million, or 169%, to $2.7 million for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. This increase was primarily due to higher sales of our BAROSTIM NEO.

Gross margin decreased to 72% for the nine months ended September 30, 2021, compared to 75% for the nine months ended September 30, 2020. Gross margin for the nine months ended September 30, 2021 was lower due to a larger percentage of our revenue units coming from full systems, which require an IPG and a stimulation lead, as compared to individual IPG sales. This was partially offset by an increase in the average selling price.

Research and development expenses

R&D expenses decreased $0.2 million, or 3%, to $5.7 million for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. This was primarily driven by a $0.8 million decline in clinical study expenses, partially offset by a $0.3 million increase in compensation expenses, including salaries and other employee-related expenses, mainly as a result of increased headcount, and a $0.3 million increase in non-cash stock-based compensation expense.

Selling, general and administrative expenses

SG&A expenses increased $11.7 million, or 182%, to $18.1 million for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. This was driven by an increase of $6.3 million in compensation expenses, including salaries and commissions, and other employee-related expenses, mainly as a result of increased headcount, a $1.9 million increase in marketing and advertising expenses, primarily related to the commercialization of our BAROSTIM NEO in the U.S., $1.4 million of additional travel expenses, a $1.0 million increase in consulting expenses, and a $0.8 million increase in non-cash stock-based compensation expense.

Interest expense

Interest expense remained consistent at $1.8 million for each of the nine months ended September 30, 2021 and 2020.

Other (expense) income, net

Other expense, net was $13.4 million for the nine months ended September 30, 2021, compared to other income, net of $0.6 million for the nine months ended September 30, 2020. This change was primarily driven by a $13.7 million increase in expense related to the increase in fair value of our convertible preferred stock warrants due to the change in our common stock price from January 1, 2021 to July 2, 2021, which is the date the warrants converted to common stock warrants.

Provision for income taxes

Provision for income taxes was nominal for each of the nine months ended September 30, 2021 and 2020.

Liquidity, capital resources and plan of operations

We have incurred significant operating losses and negative cash flows from operations since our inception, and we anticipate that we will incur significant losses for at least the next several years. As of September 30, 2021 and December 31, 2020, we had cash and cash equivalents of $170.9 million and $59.1 million, respectively. For the three months ended September 30, 2021 and 2020, our net losses were $6.1 million and $3.2 million, respectively. For the nine months ended September 30, 2021 and 2020, our net losses were $32.5 million and $10.7 million, respectively. Our net cash used in operating activities for the nine months ended September 30, 2021 and 2020 was $20.7 million and $12.0 million, respectively.

Prior to the IPO, our operations were financed primarily by aggregate net proceeds from the sale of our convertible preferred stock of $383.1 million, as well as debt financings. In July 2020, we completed an equity financing pursuant to which we issued 62,500,000 shares of Series G Preferred Shares at a price of $0.80 per share, for net proceeds of $49.8 million after deducting offering expenses. In September 2019, we

entered into the Horizon loan agreement to borrow $20.0 million. On November 3, 2021, we fully repaid our outstanding principal balance of $20.0 million under the Horizon loan agreement. In January, May and August of 2019, we completed equity financings pursuant to which we issued shares of Series G Preferred Shares at a price of $0.80 per share, for net proceeds of $24.7 million. On July 2, 2021 we closed our IPO for net proceeds from the offering, after deducting the underwriting discount and other offering expenses payable by us, of $133.2 million.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our investment in our U.S. commercial infrastructure and sales forces;
- the degree and rate of market acceptance of BAROSTIM NEO and the ability for our customers to obtain appropriate levels of reimbursement;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution;
- our R&D activities for product enhancements and to expand our indications;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence of competing technologies or other adverse market developments.

We believe that our existing cash resources together with revenue will be sufficient to meet our forecasted requirements for operating liquidity, capital expenditures and debt services for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, however, we may seek to sell additional equity or enter into an additional loan agreement. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Additional financing may not be available at all, or may only be available in amounts or on terms that we do not deem to be favorable. If we are unable to obtain additional financing when needed to satisfy our liquidity requirements, we may be required to delay the commercialization and marketing of our BAROSTIM NEO.

Cash flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below:

	Nine months ended September 30 *(unaudited)*	
(in thousands)	**2021**	**2020**
Net cash (used in) provided by:		
Operating activities	$ (20,717)	$ (12,012)
Investing activities	(645)	(210)
Financing activities	133,170	49,783
Effect of exchange rate changes on cash and cash equivalents	(7)	(7)
Net change in cash and cash equivalents	$ 111,801	$ 37,554

Cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2021 was $20.7 million and consisted primarily of a net loss of $32.5 million and a decrease in net operating assets of $3.0 million, partially offset by non-cash charges of $13.3 million related to the fair value adjustment to our convertible preferred stock warrants and $1.2 million from non-cash stock-based compensation expense. Net operating assets consisted primarily of inventory, accounts receivable and accrued expenses to support the growth of our operations.

Net cash used in operating activities for the nine months ended September 30, 2020 was $12.0 million and consisted primarily of a net loss of $10.7 million and a decrease in net operating assets of $1.3 million. Net operating assets consisted primarily of inventory, accounts receivable, accounts payable and accrued expenses to support the growth of our operations.

Cash used in investing activities:

Cash used in investing activities was $0.6 million and $0.2 million for the nine months ended September 30, 2021 and 2020, respectively, and consisted of purchases of property and equipment.

Cash provided by financing activities:

Net cash provided by financing activities for the nine months ended September 30, 2021 was $133.2 million and consisted primarily of proceeds from the issuance of common stock of $133.2 million.

Net cash provided by financing activities for the nine months ended September 30, 2020 was $49.8 million and consisted entirely of proceeds from the issuance of Series G Preferred Shares.

Indebtedness

In September 2019, we entered into the Horizon loan agreement under which we borrowed $20.0 million, which is the maximum borrowing under the Horizon loan agreement. Amounts outstanding under the Horizon loan agreement bear interest at a floating per annum rate equal to 10% plus the amount by which the 30-day U.S. dollar LIBOR rate on the first business day of the month exceeds 2.2%. The Horizon loan agreement initially required interest only payments through October 2021 and then 36 monthly principal and interest payments beginning in November 2021. In August 2020, we entered into an amended agreement with Horizon to extend the interest only period through April 2022, followed by 30 monthly principal and interest payments beginning May 2022. A final payment of $0.7 million, equal to 3.5% of the original principal, is due to be paid in October 2024. The Horizon loan agreement initially required us to maintain cash on deposit of not less than $5.0 million in accounts over which Horizon maintained an account control agreement. This minimum cash on deposit requirement was released in July 2020 following the satisfaction of a financing milestone. The borrowings are collateralized by all or substantially all of our assets, including our intellectual property portfolio. The Horizon loan agreement contains certain financial covenants, including a minimum U.S. revenue requirement of approximately $5.9 million during the year ended December 31, 2021, approximately $14.6 million during the year ended December 31, 2022 and $5.0 million during each calendar quarter thereafter; certain negative covenants, including a requirement that we not receive a final disapproval letter from the FDA for use of BAROSTIM NEO in certain other HF patients upon our request for additional labeling based upon the results of the post-market stage of our BeAT-HF pivotal trial; and various restrictive covenants, including a restriction on the payment of dividends. We were in compliance with these covenants as of September 30, 2021. The amount outstanding under the Horizon loan agreement as of September 30, 2021 was $20.0 million.

Contractual obligations and commitments

There have been no material changes to our contractual obligations as of September 30, 2021, as compared to those disclosed in the final prospectus for the IPO filed with the SEC pursuant to Rule 424(b) on July 1, 2021.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical accounting policies and estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires our management to make estimates and judgments that affect the amounts reported in our condensed consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable and supportable under the circumstances. The results of this evaluation then form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions, and such differences may be material to our condensed consolidated financial statements.

While our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Stock-based compensation

We maintain an equity incentive plan that was adopted in 2001 to provide long-term incentives for employees, consultants, and members of the Board of Directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors. In connection with the IPO, we adopted the 2021 Plan under which we may grant equity incentive awards to eligible employees (including our named executive officers), non-employee directors and consultants in order to enable us to obtain and retain services of these individuals, which we deem as essential to our long-term success.

We recognize equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* (“ASC 718”). ASC 718 requires all equity-based compensation awards to employees and nonemployee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. We estimate the grant date fair value of stock options using the Black-Scholes option pricing model. We use an estimate of the value of our common stock, with the assistance of an independent appraiser, to determine the fair value of options.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the fair value of common stock (ii) the expected share price volatility, (iii) the expected term of the award, (iv) the risk-free interest rate and (v) the expected dividend yield.

- Fair value of common stock — Given the absence of a public trading market for our common stock prior to the IPO, the fair value of our common stock was determined by our Board of Directors with the

assistance of an unrelated third-party valuation firm. The valuation was determined in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. For the valuation as of the date of pricing of the IPO, the fair value of our common stock was determined by our Board of Directors to be the public offering price of the shares of common stock issued in the IPO. For valuations after the completion of the IPO, our Board of Directors will determine the fair value of each share of common stock based on the closing price of our common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.

- Expected share price volatility — Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar (guideline) companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of guideline companies have characteristics similar to us, including stage of product development and focus on the life science industry.

- Expected term of an award — Determined based on our analysis of historical exercise behavior while taking into consideration various participant demographics and option characteristics. We utilize the simplified method to develop the estimate of the expected term.

- Risk-free interest rate — Based on a treasury instrument whose term is consistent with the expected term of the stock options.

- Expected dividend yield — We assume an expected dividend yield of zero, as we have never paid dividends and have no current plans to pay any dividends on our common stock.

We estimate pre-vesting forfeitures at the time of grant by analyzing historical data and revise those estimates in subsequent periods if actual forfeitures differ from those estimates or if they are likely to change. We expense the fair value of our equity-based compensation awards granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received.

Freestanding preferred stock warrants

Warrants to purchase our preferred stock were classified as a liability on our condensed consolidated balance sheets. These warrants were subject to remeasurement at each balance sheet date and any change in fair value was recognized in other income (expense), net. As a result of the IPO, these warrants were converted to common stock warrants and the liability was reclassified to stockholders' equity.

The valuation of our warrants required the input of certain subjective assumptions, including (i) IPO probability, (ii) the future fair value of common stock, (iii) the expected share price volatility, (iv) the expected term, (v) the risk-free interest rate and (vi) the expected dividend yield.

- IPO probability — Management, along with the assistance of an unrelated third-party valuation firm, evaluated the likelihood and timing of an IPO and applied these assumptions to the determination of the future fair value of the common stock as well as the expected term assumption.

- Future fair value of common stock — Given the absence of a public trading market for our common stock prior to the IPO, the fair value of our common stock was determined by our Board of Directors with the assistance of an unrelated third-party valuation firm. The valuation was determined in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation.

- Expected share price volatility — Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a group of similar (guideline) companies that are publicly traded. The historical volatility was calculated based on a period of time commensurate with the expected term assumption. The group of guideline companies have characteristics similar to us, including stage of product development and focus on the life science industry.

- Expected term — The expected term of the warrant was driven by the probability and timing of an IPO.

- Risk-free interest rate — Based on a treasury instrument whose term is consistent with the expected term of the stock options.

- Expected dividend yield — We assumed an expected dividend yield of zero, as we have never paid dividends and have no current plans to pay any dividends on our common stock.

JOBS Act accounting election

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

Recent accounting pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. We do not currently use or plan to use financial derivatives in our investment portfolio.

Additionally, the interest rate for our outstanding debt is variable. If overall interest rates had increased by 100 basis points during the periods presented, our interest expense would not have been materially affected.

Foreign currency exchange rate risk

To date, a majority of our revenue and a portion of our operating expenses are incurred outside the U.S. are denominated in foreign currencies and are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the Euro. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statements of operations and comprehensive loss. To date, foreign currency transaction realized gains and losses have not been material to our condensed consolidated financial statements, and we have not engaged in any foreign currency hedging transactions. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates.

Inflation risk

Inflationary factors, such as increases in our cost of goods sold and operating expenses, may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin and selling and marketing and operating expenses as a percentage of our revenue if the selling prices of our products do not increase as much as or more than these increased costs.

Credit risk

As of September 30, 2021 and December 31, 2020, our cash and cash equivalents were maintained with one financial institution in the U.S., and our current deposits are likely in excess of insured limits. We believe this institution has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and other procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our reputation, business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks related to our business

We have a history of significant losses, which we expect to continue, and we may not be able to achieve or sustain profitability. If we do not achieve and sustain profitability, our financial condition could suffer.

We have experienced significant net losses since our inception and we expect to continue to incur losses for the foreseeable future. We incurred net losses of $14.1 million and $14.6 million for the years ended December 31, 2020 and 2019, respectively. We incurred net losses of $6.1 million and $32.5 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2021 and December 31, 2020, our accumulated deficit was $384.2 million and $351.7 million, respectively. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we grow our U.S. commercial sales force and expand our marketing efforts to increase adoption of our BAROSTIM NEO, expand existing relationships with our customers, add new features to our BAROSTIM NEO, obtain regulatory clearances or approvals for our planned or future products and conduct clinical trials on our existing and planned or future products. In addition, we expect our general and administrative expenses to increase following the IPO due to the additional costs associated with being a public company.

Until our recent IPO, we financed our operations primarily through convertible preferred stock financings and amounts borrowed under the Horizon loan agreement (as defined above). We have devoted substantially all of our financial resources to research and development activities as well as general and administrative expenses associated with our operations, including clinical and regulatory initiatives to obtain marketing approval. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our expected future operating losses, combined with our prior operating losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

We have a limited history operating as a commercial company and are highly dependent on a single product, BAROSTIM NEO. The failure to obtain market acceptance in the U.S. for BAROSTIM NEO would negatively impact our business, liquidity and results of operations.

Since our inception, we have generated minimal revenue as our activities have consisted primarily of developing our BAROSTIM Therapy, conducting our BeAT-HF pre-market and post-market pivotal studies in

the U.S. and filing for regulatory approvals. We first commercialized our BAROSTIM NEO in the European Economic Area (“EEA”) in 2012 and in the U.S. in 2020 and therefore do not have a long history operating as a commercial company. We expect substantially all of our revenue to continue to be derived from sales of BAROSTIM NEO for the foreseeable future, the majority of which will be generated in the U.S. Because of its recent commercial introduction in the U.S., our BAROSTIM NEO has limited product and brand recognition. In addition, demand for our BAROSTIM NEO may decline or may not increase as quickly as we expect. If we are unable to achieve significant market acceptance in the U.S. for BAROSTIM NEO, our results of operations will be adversely affected. Because we do not yet have other products currently in development, if we are unsuccessful in commercializing BAROSTIM NEO or are unable to market BAROSTIM NEO as a result of a quality problem, failure to maintain regulatory approvals, unexpected or serious complications or other unforeseen negative effects related to BAROSTIM NEO or the other factors discussed in these risk factors, we would lose our main source of revenue, and our business, reputation, liquidity and results of operations will be materially and adversely affected.

We have limited commercial sales experience marketing and selling our BAROSTIM NEO, and if we are unable to establish and maintain sales and marketing capabilities, we will be unable to successfully commercialize our BAROSTIM NEO or generate sustained and increasing product revenue.

We currently have a limited sales and marketing organization. As a result, we have limited experience marketing and selling our BAROSTIM NEO. In order to generate future revenue growth, we plan to expand the size and geographic scope of our U.S. direct sales and marketing organization. In order to increase our sales and marketing efforts, we will need to retain, grow and develop a substantial number of direct sales personnel. We intend to make a significant investment in recruiting and training sales representatives for our commercialization effort in the U.S. There is significant competition for sales personnel experienced in relevant medical device sales. Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Because the competition for direct medical sales personnel is high, we cannot be certain we will be able to hire and retain additional sales personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating revenue. Any of these risks may adversely affect our business.

We must demonstrate to physicians and patients the merits of our BAROSTIM NEO.

Physicians play a significant role in determining the course of a patient's treatment and, subsequently, the type of product that will be used to treat a patient. As a result, our success depends, in large part, on effectively marketing BAROSTIM NEO to physicians. In order for us to sell BAROSTIM NEO, we must successfully demonstrate to physicians and patients the merits of BAROSTIM Therapy for use in treating patients with HFrEF. Specifically, BAROSTIM NEO provides symptomatic relief for patients with NYHA Class III or II (with recent history of III), have a LVEF ≤ 35% and a NT-proBNP < 1,600 pg/ml. Acceptance of BAROSTIM NEO depends on educating physicians as to the distinctive characteristics, perceived benefits, safety, ease of use and cost-effectiveness of BAROSTIM NEO, and communicating to physicians the proper application of our BAROSTIM Therapy for patients who meet BAROSTIM NEO's eligibility criteria. If we are not successful in convincing physicians of the merits of our BAROSTIM Therapy, they may not use BAROSTIM NEO and we may be unable to increase our sales, sustain our growth or achieve profitability.

In addition, physicians typically need to perform several procedures to become comfortable using BAROSTIM NEO. If a physician experiences difficulties during an initial procedure or otherwise, that physician may be less likely to continue to use our product or to recommend it to other physicians. It is critical to the success of our commercialization efforts to educate physicians on the proper use of BAROSTIM NEO, and to provide them with adequate product support during clinical procedures. If we do not provide support to physicians or do not adequately educate physicians on the benefits and proper use of BAROSTIM NEO, physicians may not use or advocate for our BAROSTIM NEO. In such circumstances, our results of operations would be materially adversely affected.

Patients may not choose or be able to receive our BAROSTIM NEO if, among other potential reasons, they are reluctant to receive an implantable device as opposed to an alternative, non-implantable treatment, they are worried about potential adverse effects of our BAROSTIM NEO, or they are unable to obtain adequate third-party coverage or reimbursement.

If third-party payors do not provide adequate coverage and reimbursement for the use of BAROSTIM NEO, our revenue will be negatively impacted.

Our success in marketing BAROSTIM NEO depends and will continue to depend in large part on whether U.S. and international government health administrative authorities, private health insurers and other organizations adequately cover and reimburse customers for the cost of our products. In the U.S., we expect to derive nearly all our revenue from sales of BAROSTIM NEO to hospitals that typically bill various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, to cover all or a portion of the costs and fees associated with procedures using BAROSTIM NEO and bill patients for any applicable deductibles or co-payments. Access to adequate coverage and reimbursement for procedures using BAROSTIM NEO by third-party payors is essential to the acceptance of our products by our customers.

Payors in the U.S. generally require hospitals and physicians to identify the proper CPT codes for the service for which they are seeking reimbursement. Procedures using BAROSTIM NEO are currently mapped to CPT code 0266T for the implantation of the device, which is a Category III CPT code. While customers are currently being reimbursed for our procedure, this may not continue in the future, as payors may determine this Category III CPT code to be investigational. This uncertainty could result in some of our target customers being unwilling to adopt BAROSTIM NEO over more established or lower cost therapeutic alternatives. While we intend to request that our codes be promoted to Category I by the American Medical Association, there can be no assurance that such efforts will be successful.

Medicare reimbursement levels are important to increasing adoption of BAROSTIM NEO because nearly two-thirds of the target patient population for BAROSTIM NEO is over the age of 65. Effective January 2021, CMS awarded BAROSTIM NEO a Transitional Pass-Through (“TPT”) payment for outpatient procedures that adds the device cost as a pass-through payment to the calculated procedure payment. The calculated procedure payment depends on many factors, including the location of the hospitals and their billing practices, and may not adequately cover hospital costs associated with the procedure. In addition, CMS awarded BAROSTIM NEO a New Technology Add-on Payment (“NTAP”) for inpatient procedures, which took effect in October 2020. The NTAP is for 65% of the device cost and is incremental to the standard payment provided for the implant procedure. Hospitals are responsible for billing for the procedures to receive the additional payment, when such increase in payment is necessary, and there can be no assurance that hospitals will accurately perform these billing procedures. The TPT payment and the NTAP are only effective for up to three years. While we intend to request that BAROSTIM NEO be reclassified into a higher Medicare reimbursement level, there can be no assurance that such efforts will be successful. Any future decline in the amount Medicare is willing to reimburse our customers for procedures using BAROSTIM NEO could make it difficult for new customers to adopt BAROSTIM NEO and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the U.S., no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process for physicians as well as hospitals that often requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. Accordingly, until such time as BAROSTIM NEO gains broader acceptance by third-party payors as a treatment for HFrEF, hospitals and physicians may encounter delays and additional administrative burdens, such as the submission of supporting documentation, in obtaining reimbursement. Such delays and additional burdens may make it less likely for physicians and hospitals to adopt BAROSTIM NEO. Any future decline in the amount third-party payors are willing to reimburse our customers for procedures using BAROSTIM NEO could make it difficult for new customers to adopt BAROSTIM NEO and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. If sufficient coverage and reimbursement is not available for our current or future products, in either the U.S. or internationally, the demand for our products and our revenues will be adversely affected.

Our industry is highly competitive. If our competitors, many of which are large, well-established companies with substantially greater resources than us and have a long history of competing in the HF market, are better able to develop and market products that are safer, more effective, less costly, easier to use or otherwise more attractive than BAROSTIM NEO, our business will be adversely impacted.

The medical device industry is highly competitive and subject to technological change. Our success depends, in part, upon our ability to establish a competitive position in the market by securing broad market acceptance of our BAROSTIM Therapy and BAROSTIM NEO for the treatment of HFrEF. Any product we develop that achieves regulatory clearance or approval, including BAROSTIM NEO, will have to compete for market acceptance and market share. We believe that the primary competitive factors in the market are demonstrated clinical effectiveness, product safety, reliability and durability, ease of use, product support and service, minimal side effects and salesforce experience and relationships. Many of our current and potential competitors that are addressing other HF indications are publicly traded, or are divisions of publicly-traded, established medical device companies that have substantially greater financial, technical, sales and marketing resources than we do, such as Medtronic plc, Boston Scientific Corporation, Abbott Laboratories and LivaNova PLC. We may also face competition from other competitors, such as Impulse Dynamics, which is a private company with a medical device indicated for a subset of our target patient population, or companies with active system development programs that may emerge in the future. Many of the companies developing or marketing competing products enjoy several advantages over us, including, among others:

- more experienced sales forces;
- greater name recognition;
- more established sales and marketing programs and distribution networks;

- earlier regulatory approval;
- long established relationships with physicians and hospitals;
- significant patent portfolios, including issued U.S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third-party suppliers and distributors;
- the ability to acquire and integrate our competitors and/or their technology;
- demonstrated ability to develop product enhancements and new product offerings;
- established history of product reliability, safety and durability;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- greater financial and human resources for product development, sales, and marketing; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products.

Our competitors may develop and patent processes or products earlier than us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products more rapidly than us or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition in recruiting and retaining qualified sales, scientific and management personnel, establishing clinical trial sites and enrolling patients in clinical studies. If our competitors are more successful than us in these matters, our business may be harmed. In addition, we face a particular challenge overcoming the long-standing practices by some physicians of using the products of our larger, more established competitors. Physicians who have completed many successful implants using the products made by these competitors may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try and subsequently adopt our product, then our revenue growth will slow or decline.

If we fail to receive access to hospitals, our sales may decrease.

In the U.S., in order for physicians to use BAROSTIM NEO, we expect that the hospitals where these physicians treat patients will typically require us to enter into purchasing contracts. This process can be lengthy, time-consuming and require extensive negotiations and management time, which could include an approval by a customer's value analysis committee. In the EU, from time to time certain institutions require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospitals via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

We are dependent upon third-party manufacturers and suppliers, and in some cases a limited number of suppliers, making us vulnerable to supply shortages, loss or degradation in performance of the suppliers and price fluctuations, which could harm our business.

We currently source certain components for our BAROSTIM NEO from a limited number of suppliers. Our ability to supply BAROSTIM NEO commercially depends, in part, on our ability to obtain a supply of these components that has been manufactured in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have not entered into manufacturing, supply or quality agreements with any of our limited suppliers, some of which supply components critical to our products, such as modules, batteries and electrodes. We currently have no plans to enter into any such contracts and we cannot guarantee that our suppliers will be able to meet our demand for their products and services, either because of the nature of our arrangements with those suppliers, our limited experience with those suppliers, or due to our relative importance as a customer to those suppliers. Further, due to our limited operating history and expected future expansion, it may be difficult for us to assess their ability to timely meet our demand in the future based on past performance.

Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including, among others:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- we may not be able to obtain an adequate supply of components in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of BAROSTIM NEO or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components or suppliers may require product redesign and possibly submission to the FDA, EEA or other foreign regulatory bodies, which could significantly impede or delay our commercial activities; one or more of our limited source suppliers may be unwilling or unable to supply components of BAROSTIM NEO;
- other customers may use fair or unfair negotiation tactics and/or pressures to impede our use of the supplier;
- we do not conduct formal environmental, social or governance due diligence on our supply chain and thus may not be aware if our suppliers pose such risks;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

Establishing additional or replacement suppliers for the components or processes used in BAROSTIM NEO, if required, could be time-consuming and expensive. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the limited sourced components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders. Given our reliance on certain limited source suppliers, we are especially susceptible to supply shortages because we have limited alternate suppliers currently available.

Manufacturing risks may adversely affect our ability to manufacture our product and could reduce our gross margin and profitability.

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers, including manufacturing compliance with federal and state regulations;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facility.

If demand for BAROSTIM NEO increases, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our product candidates in development to share product features and components with BAROSTIM NEO, manufacturing of these product candidates may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these product candidates at a cost or in quantities sufficient to make these product candidates commercially viable. Any of these factors may affect our ability to manufacture our product and could reduce our gross margin and profitability.

We operate at a facility in one location and any disruption at this facility could harm our business.

Our principal offices and our only manufacturing facility are located in Minneapolis, Minnesota. Substantially all of our operations are conducted at this location, including our manufacturing processes, research, development and engineering activities, customer and technical support and management and administrative functions. In addition, substantially all of our inventory of component supplies and finished goods is held at the manufacturing facility. Vandalism, terrorism or a natural or other disaster, such as a fire or flood, could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information and cause us to incur additional expenses. Our manufacturing facility in Minneapolis, Minnesota is our only manufacturing facility, and if it is damaged or rendered inoperable or inaccessible due to political, social or economic upheaval or due to natural or other disasters, it would be difficult or impossible for us to manufacture our product for a period of time, which may lead to a loss of customers and significant impairment of our financial condition and operating results.

We take precautions to safeguard this facility, including acquiring insurance, employing back-up generators, adopting health and safety protocols and utilizing off-site storage of computer data. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facility may harm our business, financial condition and operating results.

A pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the U.S. or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries and all 50 states within the U.S. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by decreasing and delaying the number of procedures performed using our BAROSTIM NEO, and the pandemic may continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our BAROSTIM NEO decreased significantly when healthcare organizations in the U.S. prioritized the treatment of patients with COVID-19 or altered their operations to prepare for and respond to the pandemic. We believe the COVID-19 pandemic has also negatively impacted the number of HFrEF diagnoses as hospitals focus on COVID-19 and as patients postpone healthcare visits and treatments. Specifically, a significant number of procedures using our products were postponed or cancelled beginning in March 2020.

Numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions have resulted in reduced operations at our headquarters, slowdowns and delays, travel restrictions and cancellation of events and have restricted the ability of our front-line sales representatives to attend procedures in which our products are used, among other effects, thereby negatively impacting our operations. Other disruptions or potential disruptions include restrictions on the ability of our sales representatives and other personnel to travel and access customers for training and case support; inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory bodies; delays in clinical trials and studies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; restrictions in our ability to ship our products to customers; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; and additional government requirements or other incremental mitigation efforts that may impact our or our suppliers’ capacity to manufacture our products. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and its variants and the durability of immunity offered by vaccines developed to prevent infection, as well as other actions to contain COVID-19 and its variants or treat its impact, among others.

While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may in the future result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business as hospitals curtail and reduce capital and overall spending. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition.

Sales of BAROSTIM NEO outside the U.S. represented a majority of our revenue from sales in the year ended December 31, 2020. In 2012, we began selling BAROSTIM NEO in the EEA directly to hospitals and through distributors. The sale and shipment of BAROSTIM NEO across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include, among others:

- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors, or any of our third-party suppliers;
- reduced or varied protection for intellectual property rights in some countries;
- potential pricing pressure;
- a shortage of high-quality sales representatives and distributors;
- competitive disadvantage to competition with established business and customer relationships;
- foreign currency exchange rate fluctuations;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of U.S. and foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity; and
- the imposition of new trade restrictions.

If any of these risks are realized, our sales in non-U.S. jurisdictions may be adversely affected and our results of operations would suffer.

Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell BAROSTIM NEO at prices necessary to support our current business strategies.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for price concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our future customers, which may exert further downward pressure on the prices of BAROSTIM NEO.

If we fail to properly manage our growth effectively, our business could suffer.

We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, the hiring of our direct sales force requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

To achieve our revenue goals, we must successfully increase manufacturing output to meet expected customer demand. We may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, among other problems. Any of these problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate our revenue.

Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure.

In order to manage our operations and growth we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and may have an adverse effect on our business, financial condition and results of operations.

If clinical studies for future indications do not produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere, we will be unable to commercialize our products for these indications.

We will likely need to conduct additional clinical studies in the future to support approval for new indications. For example, we are currently pursuing a morbidity and mortality indication for patients with HFrEF, which, if successful, could significantly expand our addressable patient population. However, we cannot assure you that the morbidity and mortality data will be sufficient to allow us to achieve FDA approval for expansion of this indication. In addition, if the morbidity and mortality data is perceived to be negative, such data may impact the adoption of BAROSTIM NEO, notwithstanding our existing clinical data and FDA approval. Clinical testing takes many years, is expensive and carries uncertain outcomes. The initiation and completion of any of these studies, including the post-market stage of our BeAT-HF pivotal trial, may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards ("IRBs"), ethics committees, EU competent authorities or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience serious or unexpected adverse side effects for a variety of reasons that may or may not be related to our products such as the advanced stage of co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or perform in a manner inconsistent with the investigator agreement, clinical study protocol, good clinical practices, other FDA, IRB or ethics committee requirements, and EEA Member State or other foreign regulations governing clinical trials;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;
- the study design is inadequate to demonstrate safety and efficacy; or
- the statistical endpoints are not met.

Clinical trials can fail at any stage. Our clinical studies, including the post-market stage of our BeAT-HF pivotal trial related to the morbidity and mortality indication for patients with HFrEF, may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or non-clinical studies in addition to those we have planned. In addition, if the FDA determines for any reason, including safety or their risk-benefit analysis, that the results of the post-market stage of our BeAT-HF pivotal trial or any other future trial are negative, the FDA may decide to modify or revoke our existing approval or such data may impact the adoption of BAROSTIM NEO. Moreover, a negative perception of clinical results for one indication for use could impact the use of BAROSTIM NEO for other FDA approved and clinically supported indications for use.

We could also encounter delays if the FDA concludes that our financial relationships with investigators results in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized.

Even if our products are approved in the U.S. and the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S. or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may face product liability claims that could be costly, divert management's attention and harm our reputation.

Manufacturing and marketing of BAROSTIM NEO and clinical testing of our BAROSTIM Therapy may expose us to product liability claims. Although we have, and intend to maintain, liability insurance, the coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. Further, interpretation of product liability laws may change in the future due to court rulings. It is possible evolving interpretations of product liability laws could further expose us to increased litigation risk in connection with our products. These product liability claims could, among other things, divert management's attention from our primary business and negatively affect our reputation, continued product sales, and our ability to obtain and maintain regulatory approval for our products.

We may in the future become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, thereby hindering our ability to effectively commercialize our existing or future products. If we are unable to obtain, maintain, protect, and enforce our intellectual property, our business will be negatively affected.

The market for medical devices is subject to rapid technological change and frequent litigation regarding patent and other intellectual property rights. It is possible that our patents or licenses may not withstand challenges made by others or protect our rights adequately.

Our success depends in large part on our ability to secure effective patent protection for our products and processes in the U.S. and internationally. We have filed and intend to continue to file patent applications for various aspects of our technology and trademark applications to protect our brand and business. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products or services that misappropriate our technology and/or infringe our intellectual property to compete with our products.

However, we face the risks that:

- We may fail to secure necessary patents, potentially permitting competitors to market competing products and make, use or sell products that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete.
- Our already-granted patents and any future patents may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us, and they may be re-examined or invalidated, and/or may be found to be unenforceable or not cover competing products.
- Though an issued patent is presumed valid and enforceable, it may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. For example, third parties may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have the freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the U.S. Patent and Trademark Office (the “USPTO”), to determine priority of invention in the U.S. There may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.
- Patent law is constantly evolving, can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the U.S. and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Any changes may materially affect our patents or patent applications, our ability to obtain patents or the patents and patent applications of our licensors. Future protection for our proprietary rights is uncertain because legal means affords only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our financial condition and results of operations.
- Monitoring unauthorized uses of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors’ products and services, and may in the future seek to enforce our patents or other proprietary rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products that incorporate our product features, which could reduce demand for our products. In addition, we may need to defend our patents from third-party challenges, or we may need to initiate infringement claims or litigation. In an infringement proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable or that the patent in question does not cover the technology at issue. Such an adverse result could place one or

more of our patents at risk of being invalidated or interpreted narrowly. Our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us. Further, litigation risks exposure of or compromising our confidential information.

- Any litigation or claim can be costly and time consuming and could place a significant strain on our financial resources, divert the attention of management and harm our reputation, which could have an adverse effect on our financial condition and results of operations.
- We may be forced to enter into cross-license agreements with competitors in order to manufacture, use, sell, import and export products or services that are covered by our competitors' intellectual property rights. If our intellectual property is required to enter such cross-license agreements, it may compromise the value of our intellectual property due to the fact that our competitors may be able to manufacture, use, sell, import and export our patented technology.

For additional information regarding risks related to our intellectual property, see "Risks Related to Intellectual Property."

If we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel.

Our future success depends, in part, on our ability to continue to retain our executive officers and other key employees and recruit and hire new employees. All of our executive officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. In particular, we are highly dependent upon our management team, especially our President and Chief Executive Officer and the rest of our senior management. The replacement of any of our key personnel likely would involve significant time and costs, may significantly delay or prevent the achievement of our business objectives and may harm our business. In addition, we do not carry any "key person" insurance policies that could offset potential loss of service under applicable circumstances.

In addition, many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Further, our employees' ability to exercise those options and sell their stock in a public market after the expiration of applicable lock-up agreements may result in a higher-than-normal turnover rate.

Our future success also depends on our ability to retain executive officers and other key employees and attract new key employees. Many executive officers and employees in the medical device industry are subject to strict non-compete or confidentiality agreements with their employers. In addition, some of our existing and future employees are or may be subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non-compete agreements or initiate litigation based on such confidentiality agreements. Such litigation, whether or not meritorious, may impede our ability to attract or use executive officers and other key employees who have been employed by our competitors and may result in intellectual property claims against us.

Our Horizon loan agreement contains restrictions that limit our flexibility in operating our business.

In September 2019, we entered into the Horizon loan agreement, under which we borrowed $20 million, which is the maximum borrowing under the Horizon loan agreement.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness.

The Horizon loan agreement also contains various covenants that limit our ability to engage in specified types of transactions and take certain actions. Subject to limited exceptions, these covenants limit our ability to, among other things:

- convey, sell, lease, or otherwise dispose of our assets;
- create, incur, assume or permit to exist additional indebtedness or liens;
- pay dividends on, repurchase or make distributions with respect to our capital stock;
- make specified investments (including loans and advances);
- merge, consolidate or liquidate; and
- enter into certain transactions with our affiliates.

In addition, the Horizon loan agreement contains certain financial covenants, including a minimum U.S. revenue requirement of approximately $5.9 million during the year ended December 31, 2021, approximately $14.6 million during the year ended December 31, 2022 and $5.0 million during each calendar quarter thereafter, as well as certain negative covenants, including a requirement that we not receive a final disapproval letter from the FDA for use of BAROSTIM NEO in certain other HF patients upon our request for additional labeling based upon the results of the post-market stage of our BeAT-HF pivotal trial. The covenants in the Horizon loan agreement may limit our ability to take certain actions and, in the event that we breach one or more covenants, our lender may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate the commitment to extend further credit and foreclose on the collateral granted to it to secure such indebtedness. The borrowings under the Horizon loan agreement are collateralized by substantially all of our assets, including our intellectual property portfolio.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, marketing, procurement and supply chain, manufacturing and distribution. We use enterprise information technology systems to record, process and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal and tax requirements. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

If important assumptions about the potential market for our product are inaccurate, or if we have failed to understand what people with HF are seeking in a treatment, we may not be able to increase our revenue or achieve profitability.

Our business strategy was developed based on a number of important assumptions about the HF market in general, any one or more of which may prove to be inaccurate. For example, we believe that the benefits of BAROSTIM NEO as compared to other common HF devices will continue to drive growth in the market for BAROSTIM NEO. Despite our review of studies reporting on the trends of HF incidence in the U.S., the actual incidence of HF, and the actual demand for our product or competitive products, could differ materially from our expectations. In addition, our strategy of focusing exclusively on patients with HFrEF who are looking for an improvement in the symptoms associated with HFrEF may limit our ability to increase sales or achieve profitability, especially if there are any significant clinical breakthroughs or product or drug introductions that significantly delay or reduce the need for heart disease therapy. Moreover, a percentage of our indicated patients may be ineligible to undergo a BAROSTIM NEO procedure if they have certain co-morbidities or other disqualifying factors as determined by their physicians.

Our estimates of the annual total addressable market for BAROSTIM NEO are based on a number of internal and third-party estimates, including, without limitation, the number of patients with HFrEF and the assumed prices at which we can sell our device. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our BAROSTIM NEO may prove to be incorrect. If the actual number of patients who would benefit from our product, the price at which we can sell our product, or the annual total addressable market for our product is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and, more recently, the global COVID-19 pandemic caused, and is continuing to cause, disruptions in the capital and credit markets, severe supply shortages and reduced hospital and clinical visits, including due to temporary shutdowns under federal, state and local mandates. A severe or prolonged economic downturn, such as the global financial crisis and COVID-19 pandemic, has resulted in and could in the future result in a variety of risks to our business, including weakened demand for BAROSTIM NEO, a delayed time to meet clinical endpoints and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy has strained and could in the future strain our manufacturers or suppliers, resulting in supply disruption, or causing our customers to delay making payments for our services. Certain of the foregoing could have harmed and could in the future harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions may further affect our business.

We may enter into strategic collaborations, in-licensing arrangements or alliances with third parties that may not result in the development of commercially viable products or the generation of significant future revenue.

In the ordinary course of our business, we may enter into strategic collaborations, in-licensing arrangements or alliances to develop product candidates and to pursue new markets. Proposing, negotiating and implementing strategic collaborations, in-licensing arrangements or alliances may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. We have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could impair our ability to execute our business strategies.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our BAROSTIM platform technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including, among others:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our inability to integrate any acquired products or technologies effectively could impair our ability to execute our business strategies. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

Risks related to intellectual property

We may in the future become involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive, time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.

Our success depends in part on not infringing the patents or violating the other proprietary rights of others. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical device industry. Whether merited or not, it is possible that third parties controlling U.S. and foreign patents allege such patents cover our products. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, sell, or export our products. These competitors may have one or more patents for which they can threaten or initiate patent infringement actions against us or any of our third-party suppliers. Further, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages or attorneys' fees. From time to time and in the ordinary course of business, we may develop noninfringement or invalidity positions with respect to third-party patents, which may or may not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

We may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents or other intellectual property rights or misappropriation of trade secrets, or offering licenses to such intellectual property. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could require us to do one or more of the following:

- stop selling, making, using or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;

- find non-infringing substitute products, which could be costly and create significant delay due to the need for FDA regulatory clearance;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive or infeasible.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in our industry grows, the possibility of intellectual property infringement claims against us increases.

In addition, we may indemnify our customers, suppliers and international distributors against claims relating to the infringement of the intellectual property rights of third parties relating to our products, methods and/or manufacturing processes. Third parties may assert infringement claims against our customers, suppliers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, suppliers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, or our suppliers may be forced to stop providing us with products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications.

Furthermore, the U.S. and foreign courts are continually interpreting various aspects of patent law. We cannot predict with any reasonable certainty how the evolution of the interpretation of these laws will affect our business. However, it is possible that changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-disclosure or confidentiality agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-disclosure or confidentiality agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor, resulting in litigation. Even if we are successful in defending against these claims, the litigation could be costly and a distraction to management. If we are unsuccessful in defending against these claims, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have registered trademarks similar and identical to our trademarks in foreign jurisdictions, and may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our consultants and vendors, and our employees. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be sufficient. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are reluctant or unwilling to enforce trade secret protection.

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent or superior to our proprietary technology. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those with whom they share it, from using that technology or information to compete with us and our competitive position could be adversely affected. If our intellectual property is not adequately protected to protect our market against competitors' products and methods, our competitive position and business could be adversely affected.

Risks related to our financial and operating results

We may be required to obtain additional funds in the future, and these funds may not be available on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, and we anticipate our expenses will increase as we build a commercial sales force in the U.S., investigate the potential use of BAROSTIM NEO for the treatment of other HF conditions, continue to grow our business, and transition to operating as a public company. We believe that our growth will depend, in part, on our ability to fund our commercialization and R&D efforts. We believe that the net proceeds from the IPO, together with our existing cash, cash equivalents, short-term investments and revenue will be sufficient to meet our capital requirements and fund our operations for at least 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. As a result, we may need to seek additional funds in the future. If we are unable to raise funds on favorable terms, or at all, we may not be able to support our commercialization efforts or increase our research and development activities and the growth of our business may be negatively impacted. As a result, we may be unable to compete effectively. For the nine months ended September 30, 2021 and 2020, net cash used in operating activities was $20.7 million and $12.0 million, respectively. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including, among others:

- the scope and timing of our investment in our U.S. commercial infrastructure and sales force;
- the costs of commercialization activities including product sales, marketing, manufacturing and distribution and hiring a direct sales and marketing team in the U.S.;
- the degree and rate of market acceptance of BAROSTIM NEO;
- the R&D activities we intend to undertake in order to pursue product enhancements and expand HF indications;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence of competing technologies or other adverse market developments.

To finance certain of these activities, we may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We may be unable to raise funds on favorable terms, or at all.

The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If we borrow additional funds or issue debt securities, these securities could have rights superior to holders of our common stock and could contain covenants that will restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products that we otherwise would not relinquish. If we do not obtain additional resources, our ability to capitalize on business opportunities will be limited, we may be unable to compete effectively and the growth of our business will be adversely affected.

Our operating results may vary significantly annually or from quarter to quarter, which may negatively impact our stock price in the future.

Our revenue and results of operations may fluctuate annually or from quarter to quarter due to, among others, the following reasons:

- physician and payor acceptance of BAROSTIM NEO and our BAROSTIM Therapy;
- the timing, expense and results of research and development activities, clinical trials and regulatory approvals;
- fluctuations in our expenses associated with expanding our commercial operations and operating as a public company;
- the introduction of new products and technologies by our competitors;
- the productivity of our sales representatives;
- supplier, manufacturing or quality problems with our products;
- the timing of stocking orders from our distributors;
- changes in our pricing policies or in the pricing policies of our competitors or suppliers; and
- changes in coverage amounts or government and third-party payors' reimbursement policies.

Because of these and other factors, it is possible that our operating results will not meet investor expectations or those of public market analysts.

Any unanticipated change in revenues or operating results is likely to cause our stock price to fluctuate. New information may cause investors and analysts to revalue our business, which could also cause a fluctuation in our stock price.

We are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.

Our product consists of a substantial number of individual components. In order to market and sell BAROSTIM NEO effectively, we often must maintain high levels of inventory. The manufacturing process requires lengthy lead times, during which components of our products may become obsolete, and we may over- or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we can produce. As compared to direct manufacturers, our dependence on third-party manufacturers for our component parts exposes us to greater lead times.

The seasonality of our business creates variance in our quarterly revenue, which makes it difficult to compare or forecast our financial results.

We expect that any revenue we generate could fluctuate from quarter to quarter as a result of timing and seasonality. We anticipate mild seasonality based on national holiday patterns specific to certain nations. These seasonal variations are difficult to predict accurately, may vary amongst different markets, and at times may be entirely unpredictable. In addition to the above factors, in the U.S. it is possible that we may experience seasonality based on patients' annual deductibility limits under their health insurance coverage. While historically seasonality has been minimal, we anticipate increased seasonality due to our increased focus on sales within the U.S. These seasonal variations are difficult to predict accurately, may vary amongst different markets and at times may be entirely unpredictable, which introduces additional risk into our business as we rely upon forecasts of customer demand to build inventory in advance of anticipated sales. In addition, we believe our limited history commercializing our products has, in part, made our seasonal patterns more difficult to discern and therefore predict.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

A portion of our current business is located outside the U.S. and, as a result, we generate revenue and incur expenses denominated in currencies other than the U.S. dollar, a majority of which is denominated in Euros. In 2019 and 2020, a majority of our total revenue was denominated in foreign currencies. As a result, changes in the exchange rates between such foreign currencies, particularly the Euro and the U.S. dollar, could materially impact our reported results of operations and distort period to period comparisons. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non-U.S. currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the trading price of our common stock could be adversely affected. In the future, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on our results of operations.

Our ability to use our net operating losses and tax credits to offset future taxable income and taxes may be subject to certain limitations, and we may not be able to utilize a significant portion of our net operating loss and tax credit carryforwards prior to their expiration.

We have generated and expect to continue to generate significant federal and state NOLs and tax credit carryforwards. As of December 31, 2020, we had federal and state NOL carryforwards of approximately $296.1 million and $88.0 million, respectively. The federal NOLs begin to expire in 2021 and state NOLs began expiring in 2020. As of December 31, 2020, we had federal and state tax credit carryforwards of approximately $8.6 million and $1.5 million, respectively. The federal and state tax credit carryforwards begin to expire in 2021 and 2028, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the legislation enacted on December 22, 2017 commonly referred to as the "Tax Cuts and Jobs Act" (the "TCJA"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs incurred in taxable years beginning after December 31, 2020 is limited. It is uncertain how various states will respond to the TCJA and the CARES Act.

In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL and specified other tax credit carryforwards, such as research and development tax credits, to offset future taxable income and taxes. We may have previously experienced, and may in the future experience, one or more "ownership changes" for purposes of the rules under Section 382 and 383 of the Code, including in connection with our IPO. If so, or if we do not generate sufficient taxable income, we may not be able to utilize a material portion of our NOLs and tax credits, even if we achieve profitability. If we are limited in our ability to use our NOLs and tax credits in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits. This could materially and adversely affect our results of operations by effectively increasing our future tax obligations.

We are subject to complex tax rules, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition.

We are subject to income and/or non-income taxes in the U.S., Switzerland, Italy, Germany, France and the Netherlands, as well as the tax laws and regulations related to such matters. Tax accounting and compliance often involves complex issues, and judgment and interpretation is required in determining our provision for income taxes and other tax liabilities as well as the application of tax laws and regulations. In that respect, many jurisdictions have detailed transfer pricing rules, which require that all transactions with related parties be priced using arm's length pricing principles within the meaning of such rules. The application of such transfer pricing rules, as well as of withholding taxes, goods and services taxes, sales taxes and other taxes is not always clear and we may be subject to tax audits relating to such rules or taxes.

We believe that our tax positions are reasonable, and our tax provisions and reserves are adequate to cover any potential liability. However, various items cannot be accurately forecasted and future events may be treated as discrete to the period in which they occur. In addition, the Internal Revenue Service or other taxing authorities may disagree with our positions. If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results, operations and future cash flow.

Changes in U.S. and non-U.S. tax laws could adversely affect our financial condition and results of operations.

The rules dealing with U.S. and non-U.S. tax matters are constantly under review by persons involved in the legislative, judicial, administrative, regulatory and related governmental processes and authorities. Changes to tax laws or the interpretation and application thereof (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. and non-U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. and non-U.S. tax laws on an investment in our common stock.

We may not be able to generate sufficient cash to service our Horizon loan agreement.

As of September 30, 2021, the aggregate principal amount outstanding under our Horizon loan agreement was $20.0 million. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to numerous risks, including the risks in this section, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot be certain that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of our Horizon loan agreement, we may be required to repay any outstanding amounts earlier than anticipated.

Risks related to regulation of our industry

BAROSTIM NEO is subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the EU legislative bodies and the EEA Member State Competent Authorities. The FDA and other U.S., EEA and foreign governmental agencies and authorities regulate and oversee, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- pre-market regulatory clearance and approval;
- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The laws and regulations to which we are subject are complex and have tended to become more stringent over time. Legislative or regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Our failure to comply with U.S. federal and state regulations or EEA or other foreign regulations applicable in the countries where we operate could lead to the issuance of warning letters or untitled letters, fines, injunctions, suspensions or loss of regulatory clearance or approvals, recalls or seizures of products, termination of distribution, or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facilities are possible. If any of these risks materialize, our business would be adversely affected.

BAROSTIM NEO is also subject to extensive governmental regulation in foreign jurisdictions, such as Europe, and our failure to comply with applicable requirements could cause our business to suffer.

In the EEA, BAROSTIM NEO must comply with the Essential Requirements laid down in Annex I to the EU Active Implantable Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to BAROSTIM NEO, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE Mark to BAROSTIM NEO, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the Essential Requirements must be based on, among other things, the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. With respect to active implantable medical devices or Class III devices, the manufacturer must conduct clinical studies to obtain the required clinical data, unless reliance on existing clinical data from equivalent devices can be justified. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

In order to continue to sell BAROSTIM NEO in Europe, we must maintain our CE Mark and continue to comply with certain EU Directives. Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body (the British Standards Institution, or BSI), which could impair our ability to market products in the EEA in the future.

Our business is subject to extensive governmental regulation that could make it more expensive and time consuming for us to bring BAROSTIM NEO to market in the U.S. and introduce new or improved products.

Our products must comply with regulatory requirements imposed by the FDA in the U.S. and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, extensive agency review processes and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We also are subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. Some of the most important requirements we must comply with include:

- the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations (Title 21 CFR);
- EU CE mark requirements;
- Medical Device Quality Management System Requirements (ISO 13485:2003);
- Occupational Safety and Health Administration requirements; and
- California Department of Health Services requirements.

Current or evolving government regulation may impede our ability to conduct clinical studies and to manufacture and sell our existing and future products. Such government regulation also could delay our marketing of new products for a considerable period of time and impose costly procedures on our activities.

Our products remain subject to strict regulatory controls on manufacturing, marketing and use. We may be forced to modify or recall a product after release in response to regulatory action or unanticipated difficulties encountered in general use. Any such action could have a material effect on the reputation of our products and on our business and financial position. Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development programs and harm our business in unforeseen ways. If this happens, we may have to incur significant costs to comply with such laws and regulations, which will harm our results of operations.

The misuse or off-label use of our product may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in inappropriate promotion.

BAROSTIM NEO has been indicated for the improvement of symptoms of HFrEF by the FDA and EEA. We may only promote or market BAROSTIM NEO for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using our product off-label when, in the physician’s independent professional medical judgment, he or she deems appropriate. There may be increased risk of injury to patients if physicians attempt to use our product off-label. Furthermore, the use of our product for indications other than those approved by the applicable regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our product or use improper techniques, potentially leading to injury and an increased risk of product liability. If our product is misused or used with improper technique, we may become subject to costly product liability claims or other litigation by our customers or their patients. In addition, if the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute inappropriate promotion, including promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Further, the advertising and promotion of our products is subject to EEA Member State laws implementing Directive 93/42/EEC concerning Medical Devices (the "EU Medical Devices Directive"), Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. EEA Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

The discovery of serious safety issues with BAROSTIM NEO, or a recall of BAROSTIM NEO either voluntarily or at the direction of the FDA or another governmental authority, could harm our reputation, business and financial results.

The FDA, the competent authorities of the EEA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety or in the event that a product poses an unacceptable risk to health. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. We may also choose to conduct a product notification or recall to inform physicians of changes to instructions for use, or if a deficiency in a device is found or suspected. A government-mandated recall or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, packaging defects or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls, which include certain notifications and corrections as well as removals, of BAROSTIM NEO could divert managerial and financial resources and could have an adverse effect on our financial condition, harm our reputation, and reduce our ability to achieve expected revenue.

In addition, the manufacturing of our products is subject to extensive post-market regulation by the FDA and foreign regulatory authorities, and any failure by us or our contract manufacturers or suppliers to comply with regulatory requirements could result in recalls, facility closures and other penalties. We and our suppliers and contract manufacturers are subject to the FDA's Quality System Regulation, and comparable foreign regulations which govern the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping and servicing of medical devices. These regulations are enforced through periodic inspections of manufacturing facilities. Any manufacturing issues at our or our suppliers' or contract manufacturers' facilities, including failure to comply with regulatory requirements, may result in warning or untitled letters, manufacturing restrictions, voluntary or mandatory recalls or corrections, fines, withdrawals of regulatory clearances or approvals, product seizures,

injunctions or the imposition of civil or criminal penalties, which would adversely affect our business results and prospects.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA and European regulators, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations.

Under the FDA medical device reporting regulations, medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the EU Medical Devices Directive (Directive 93/42/EEC), an incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or European regulators could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval, seizure of our products or delay in clearance or approval of future products.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws and regulations could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the U.S., the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), which require certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;

- state and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to increase their scrutiny of interactions between healthcare companies and healthcare providers. The Office of the Inspector General of the Department of Health and Human Services also has issued compliance program guidance for pharmaceutical manufacturers which is routinely applied to medical device companies. All of this has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry, including for medical device companies. Responding to investigations can be time and resource consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Healthcare legislative reform measures may have a material adverse effect on us.

In March 2010, the ACA was signed into law, which incorporates, among other things, comparative effectiveness research, an independent payment advisory board and payment system reforms, including shared savings pilots and other provisions, may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Additionally, on April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable (i.e., without the need for adoption of the EEA member state laws implementing them), in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among the EEA member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation became applicable in May 2020 and, among other things:

- strengthened the rules on placing devices on the market and reinforced surveillance once they are available;
- established explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improved the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

This regulation has not yet had a material effect on the way we conduct our business in the EEA. However, it is possible the regulation will change in the future and we cannot be certain that future changes will not have an adverse effect on our business operations.

Risks related to our common stock

We are incurring and will incur significantly increased costs as a result of being a public company, and our management is required to devote substantial time to compliance with our public company responsibilities, which may adversely affect our business, financial condition and results of operations.

As a public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are now subject to the reporting requirements of the Exchange Act and must comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and The Nasdaq Stock Market LLC ("Nasdaq"), including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Compliance with these requirements has and will continue to increase our legal and financial compliance costs and make some activities more time consuming and costly, which may adversely affect our business, financial condition and results of operations.

In addition, our management and other personnel must now divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an emerging growth company, as defined by the JOBS Act, and are not a non-accelerated filer. We have hired, and will need to continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and have established an internal audit function. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which would increase our general and administrative expense and could adversely affect our profitability. As a public company, it is more difficult and expensive for us to obtain director and officer liability insurance on reasonable terms. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees, or as executive officers.

We expect that the price of our common stock will fluctuate substantially, and you may not be able to resell shares of our common stock at or above the price you paid.

The market price of our common stock has been and may continue to be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and future U.S. clinical trials for BAROSTIM NEO;
- announcements of new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- our operating results;
- changes or developments in laws or regulations applicable to our products;
- any adverse changes in our relationship with any manufacturers or suppliers;
- the success of our efforts to acquire or develop additional products;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the medical device industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the U.S.;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets; and
- the loss of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for medical device stocks in particular, have experienced volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile or decreases significantly, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

We have broad discretion to determine how to use the funds raised in the IPO and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management has broad discretion over the use of proceeds from the IPO, and we could spend them in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from the IPO to continue funding the expansion of our direct sales force and commercial organization related to BAROSTIM NEO in the U.S., research and development activities related to BAROSTIM Therapy and working capital and general corporate purposes. If we do not invest or apply the proceeds of the IPO in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

An active trading market for our shares of common stock may not be sustained.

Our common stock began trading on June 30, 2021 and has a limited trading history upon which to assess whether an active public market for our shares may be sustained. The lack of an active market may impair the value of your shares or your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies or in-license new product candidates using our shares as consideration. Furthermore, there can be no guarantee that we will continue to satisfy the continued listing standards of Nasdaq. If we fail to satisfy these listing standards, we could be de-listed, which would have a negative effect on the price of our common stock.

Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price and trading volume to decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts cover us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our financial statements may not be directly comparable to other public companies.

Pursuant to the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. Because we have elected to take advantage of this provision of the JOBS Act, our financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies.

If we are unable to maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected.

To comply with the requirements of being a public company, we are undertaking and expect to continue to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We have developed and expect to continue to refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following the IPO, which will be for our fiscal year ending December 31, 2022, provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm,

to the extent we are no longer an “emerging growth company,” as defined by the JOBS Act, and are not a non-accelerated filer. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we are an emerging growth company.

Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. If we fail to develop and maintain effective internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have designed and implemented and expect to continue to refine the internal control over financial reporting required to comply with this obligation, which process will be time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or, when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, or if our internal control over financial reporting is perceived as inadequate or we are unable to produce timely or accurate financial statements, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could become subject to investigations or removal by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that these sales may occur, could result in a decrease in the market price of our common stock.

Approximately 20.3 million shares of common stock were outstanding immediately following the IPO. Of these shares, approximately 6.7 million shares of our common stock are freely tradable, without restriction.

The lock-up agreements pertaining to the IPO will expire on December 26, 2021. After the lock-up agreements expire, up to an additional approximately 13.6 million shares of common stock will be eligible for sale in the public market, approximately 9.9 million of which shares are beneficially owned by current directors, executive officers and other affiliates and may be subject to volume limitations under Rule 144 under the Securities Act. The representatives of the underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, as of September 30, 2021, approximately 2.7 million shares of common stock that are subject to outstanding options and approximately 0.7 million shares of common stock that are subject to outstanding warrants are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After the IPO, the holders of approximately 11.9 million shares of our outstanding common stock became entitled to rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. We have also registered all shares of common stock that we may issue under our equity compensation plans, which shares can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up agreements referred to above.

Our principal stockholders, management and directors (four of whom are affiliated with our principal stockholders) own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Immediately following the IPO, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 63% of our outstanding voting stock. Four of our non-employee directors are also affiliated with certain of our principal stockholders. Therefore, even after the IPO these stockholders, if they act together, will have the ability to influence us through this ownership position and matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the Company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law (the "DGCL") or any action asserting a claim against us that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation also provides that the U.S. federal district courts are the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. Under the Securities Act, federal and state courts have

concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and results of operations.

Anti-takeover provisions included in our amended and restated certificate of incorporation and amended and restated bylaws, as well as under Delaware law, could discourage a takeover.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace or remove current members of our management team. These include the following provisions that:

- permit our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, without stockholder approval, which could be used to dilute the ownership of a hostile bidder significantly;
- provide that the authorized number of directors may be changed only by resolution of our Board of Directors and that a director may only be removed with cause by the affirmative vote of the holders of at least a majority of our outstanding voting stock, voting together as a single class;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that our amended and restated bylaws may only be altered, amended or repealed by our stockholders upon the affirmative vote of a two-thirds majority of the voting power of all of our outstanding voting stock, voting together as a single class;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company;
- prohibit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and
- provide that special meetings of our stockholders may be called only by the Chairman of the board, the

Chief Executive Officer, or a majority of the Board of Directors then in office, which may delay the ability of our stockholders to force consideration by our company of a take-over proposal or to take certain corporate actions, including the removal of directors.

In addition, Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This provision could have the effect of delaying or preventing a change in control of our company, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Additionally, the terms of our Horizon loan agreement prohibit us from paying cash dividends on our capital stock. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from the IPO

On July 2, 2021, we completed our IPO and issued 8,050,000 shares of our common stock at a public offering price of $18.00 per share, which includes 1,050,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional share, for total gross proceeds from the offering, before deducting the underwriting discount and other offering expenses, of approximately $144.9 million. After deducting the underwriting discount of $10.1 million and offering expenses of $1.5 million, we received net proceeds of approximately $133.2 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates. J.P. Morgan Securities LLC, Piper Sandler & Co. and William Blair & Company, L.L.C. acted as joint book-running managers of the IPO, and Canaccord Genuity LLC acted as a lead manager for the IPO. Shares of our common stock began trading on the Nasdaq Global Select Market on June 30, 2021. The offer and sale of the shares were registered under the Securities Act on Registration Statement on Form S-1 (File No. 333-256800), which was declared effective on June 29, 2021.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated June 29, 2021, filed with the SEC on July 1, 2021 pursuant to Rule 424(b) of the Securities Act.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of CVRx, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 7, 2021)
3.2	Amended and Restated By-Laws of CVRx, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on July 7, 2021)
31.1†	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH†	Inline XBRL Taxonomy Extension Schema Document
101.CAL†	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104†	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

† Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto, duly authorized.

Date: November 8, 2021

CVRX, INC.

By: /s/ Nadim Yared
Name: Nadim Yared
Title: President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Jared Oasheim
Name: Jared Oasheim
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Nadim Yared, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CVRx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 08, 2021

By: /s/ Nadim Yared
Name: Nadim Yared
Title: President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Jared Oasheim, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CVRx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 08, 2021

By: /s/ Jared Oasheim
Name: Jared Oasheim
Title: Chief Financial Officer

Exhibit 32.1

Certification of CEO Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report of CVRx, Inc (the "Company") on Form 10-Q for the period ended September 30, 2021 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 08, 2021

By: /s/ Nadim Yared
Name: Nadim Yared
Title: President and Chief Executive Officer

Exhibit 32.2

Certification of CFO Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report of CVRx, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 08, 2021

By: /s/ Jared Oasheim
Name: Jared Oasheim
Title: Chief Financial Officer